# Program Description
# Animal Care and Use Program

## Research Service

## Boise VA Medical Center
## VA-126

## 500 W. Fort St., Boise, Idaho

## March 30, 2018

## For
## AAALAC International

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**Appendices**

## Program Description

### Instructions for Completing and Submitting the Program Description for the Institutional Animal Care and Use Program

### Section 1. Introduction

**A.** State the name of the program unit and, if applicable, its parent organization. List all organizations (schools, centers, etc.) included within the program unit.

Animal Care and Use Program, Research Service, Boise Veterans Affairs Medical Center (BVAMC)

**B.** Give a brief overview of the institution, its purpose and how the animal care and use program relates to the mission of the institution.

The Boise Veterans Affairs Medical Center (BVAMC) is a government health care institution whose mission is to care, heal, teach, and discover. Through this mission the BVAMC offers quality health care to eligible veterans, trains future health professionals, and conducts biomedical and health services research to advance the translation of biomedical science and the practice of medicine to veterans and the citizens of Idaho. The Medical Center has long been affiliated with the University of Washington, School of Medicine. This affiliation is a sharing agreement between the University of Washington and the Veterans Affairs Medical Center to provide an academic environment at the Medical Center for the faculty who are staff physicians and health care providers. This academic environment includes the opportunity for teaching by using Veterans Affairs physical, patient, and staff resources. It also provides an educational environment wherein residents and interns are provided an opportunity to experience medical care under the direction of senior faculty. This ensures that health care providers who are university faculty and staff members of the BVAMC are of high quality and meet the standards of the medical school. The Biomedical Research Program plays an important part in providing the academic environment to attract and retain quality health care providers. In this role, it is important that the ability to use animal models in research is available. We have funded investigators who are dependent upon animal research support to execute their grants and institutional research programs. There is derivative

benefit of the Animal Care and Use Program (ACUP) to many other investigators who do not require animal use in their research protocols. This is gained through collaborative efforts and association with investigators who do utilize the ACUP.

**C.** Note that AAALAC International's three primary standards are *the Guide for the Care and Use of Laboratory Animals* (*Guide*), NRC, 2011; the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* (*Ag Guide*), FASS, 2010, and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123). Other regulations and guidelines used (U.S. Department of Agriculture (USDA), Public Health Service (PHS) Policy, Good Laboratory Practice (GLP), Canadian Council on Animal Care (CCAC), etc.) may also apply. Describe which of the three primary standards and other regulations and guidelines are used as standards for the institutional animal care and use program and how they are applied. For example, an academic institution in the United States with an Office of Laboratory Animal Welfare (OLAW) Assurance may use the standards of the *Guide* and PHS Policy for all animals, the Animal Welfare Act regulations for covered species, and the *Ag Guide* for agricultural animals used in agricultural research and teaching (see also *Guide*, pp. 32-33). In the European Union, the standards applied might be the *Guide*, ETS 123, Directive 2010/63, and any country-specific regulations.

The Guide is the primary standard for animal care and use for the BVAMC. The recommendations made by this book helps determine how and to what standards the VMU humanely cares for animals. The policy and procedures developed from The Guide are followed and applied every day at the VMU. This includes such things as cleaning, environment, handling, and care of animals. We also comply with the Office of Laboratory Animal Welfare (OLAW) and have a current Public Health Service (PHS) Assurance which is also followed. It has been provided to all animal researchers and their staff. The PHS Assurance outlines is how we conduct our program to comply with OLAW and NIH. Since this is a Veterans Affairs facility, we must also comply with all VA and other federal rules and regulations pertaining to animal research, research in general, and hazardous agents. Guidance is provided through Veterans Health Administration Handbooks (VHA) as well as checklists, information and policies set by the VA's Office of Research and Development and the Office of Research Oversight. These resources are available for our program to develop our own policies and procedures on how

we conduct our program from training, running our IACUC, developing our animal protocols, reporting requirements for adverse events, research results and research noncompliance. All of these standards are applied to provide a safe and humane environment for research staff and animals.

**D.** Describe the organization and include an accurate, current, and detailed organizational chart or charts (see **Appendix 4**) detailing the lines of authority from the Institutional Official to the Attending Veterinarian, the Institutional Animal Care and Use Committee/Oversight Body (IACUC/OB), and the personnel providing animal care. Please include the title, name (*Note:* For individuals whose information is publicly available, provide the titles and names; for individuals whose information is not publicly available, you may provide titles only.), and degree (if applicable) of each individual at the level of supervisor or above. Names of animal care staff below the title of supervisor need not be included, but the titles and number of animal care personnel under each supervisor should be included. If animal care responsibility is administratively decentralized, including the management of satellite housing areas/locations, the organizational chart or charts must include all animal care programs, indicating the relationship between each administrative unit and personnel, the Attending Veterinarian, and the Institutional Official.

Research and Development (R&D) is a BVAMC service under the Office of the Chief of Staff (COS). The COS reports to the Medical Center Director (MCD) or Institutional Official (IO). R&D is headed by the Associate Chief of Staff for Research and Development (ACOS/R&D), who reports to the COS. Daily R&D operations are carried out by the Administrative Officer (AO/ACOS/R&D) who reports to the ACOS/R&D. The ACUP Manager reports to the AO/ACOS/R&D. This person manages the daily operations of the ACUP and the Veterinary Medical Unit (VMU). This manager sits on the Institutional Animal Care and Use Committee (IACUC) and the Subcommittee on Research Safety (SRS). The manager serves as the IACUC contact and communicates regularly with the principal investigators (PIs) regarding their studies.

The R&D Committee functions at the facility level and is focused on oversight of the facility research program. It is responsible for oversight and maintaining the highest ethical standards with accountability to all involved stakeholders (VHA Handbook 1200.01).

The IACUC is one of the subcommittees reporting to the R&D Committee. The IACUC is responsible for ensuring compliance with animal research regulations and guidelines (VHA Handbook 1200.07) and the PHS Assurance. The IACUC chair is a VA researcher who has active animal studies being conducted at the BVAMC.

The BVAMC has a Consultant Veterinarian (CV), who is a voting member of the IACUC, reports to the IO, works directly with the ACUP Manager, and with the PIs as needed. He also reviews all animal protocols, new and continuing.

The ACUP Manager is responsible for the daily operations of the VMU. She reports to the AO/ACOS/R&D and is a voting member of the IACUC. She has one Animal Care Technician (ACT) at 0.70 FTE, currently vacant, and a weekend/holiday ACT working with her.
The BVAMC also has a Research Compliance Officer (RCO) who works closely with the AO and ACOS of Research. He reports to the MCD and is a frequent guest at IACUC meetings.

Individuals, Titles, Credentials

(b)(6)

**E.** Identify the key institutional representatives (including, but not limited to, the Institutional Official; IACUC/OB Chairperson; Attending Veterinarian; animal program manager; individual(s) providing biosafety, chemical hazard, and radiation safety oversight; etc.); and individuals anticipated to participate in the site visit.

We anticipate the following institutional representatives will participate in the

site visit:

(b)(6)

**F.** Briefly describe the major types of research, testing, and teaching programs involving animals and note the approximate number of principal investigators and protocols involving the use of animals. As mentioned in the instructions, please complete **Appendix 5** (Animal Usage) or provide the information requested in a similar format as an Appendix.

The BVAMC currently has six principal investigators using animals in their research programs. There are six protocols involving laboratory animals. Mice are the primary animal species being used in animal research. The current Daily Animal Average Inventory and Use by Species Form are included as Appendix 1.

The major areas of research are:

1. Infectious Diseases – toxin production, interaction and inhibition; immuno-and pathogenesis and novel treatments
2. Pharmacology – drug metabolism, drug response, drug interactions

**G.** Note the source(s) of research funding (grants, contracts, etc.) involving the use of animals.

Research funding sources involving animal use include:

1. Department of Veterans Affairs
2. NIH – National Center for Research Resources

3. Merck Pharmaceuticals, Inc.
4. Motif Biosciences

**H.** List other units (divisions, institutes, areas, departments, colleges, etc.) of your organization that house and/or use animals that are not included in this Description. If any of these are contiguous, physically or operationally (e.g., same IACUC/OB, same animal care staff), with the applicant unit, describe the association. Explain why such units are not part of this program application.
*Note:* Questions regarding this section should be forwarded to the AAALAC Office.

There are no other on-site units of our organization that house and use animals.

**I.** Contract Facilities: If the institution contracts for animal care facilities or services for animals owned by the institution, the contractor and its AAALAC International accreditation status must be identified. If a contractor's animal care and use program is not accredited by AAALAC International, a brief description, following this Program Description outline, of the relevant contractor's programs and facilities must be provided. In addition, the species and approximate average number of animals housed in the contract facilities and the approximate distance between the institution's animal facility and the contract facility must be noted. Incorporation of the contractor program into the site visit schedule will be discussed with institutional representatives. If the institution does not contract for animal care facilities or services, so note.

Not applicable – BVAMC does not contract with other animal facilities or services.

**J.** Note other relevant background that will assist reviewers of this report.

Nothing of note

## Section 2. Description

### I. Animal Care and Use Program

#### A. Program Management

**1. Program Management Responsibility** [*Guide*, pp. 13-15]

**a. The Institutional Official** [*Guide* pp. 13-14]
Describe how program needs are clearly and regularly communicated to the Institutional Official by the Attending Veterinarian, IACUC/OB, and others associated with the program.

The ACUP needs are regularly communicated to the IO by the ACOS/R&D and the IACUC Chairperson during the VA IACUC Semi-Evaluation. Immediate needs are communicated to the IO by the ACOS/R&D. The consultant veterinarian reports to the IO. The IO also sits on the R&DC.

**b. Role of the Attending Veterinarian** [*Guide*, p. 14]

**i.** Describe the institutional arrangement for providing adequate veterinary care. Although individual name(s) and qualifications will be described below, identify by title the veterinarian(s) responsible for the veterinary care program, including:

- a list of responsibilities
- a description of the veterinarian's involvement in monitoring the care and use of laboratory animals
- the percentage of time devoted to supporting the animal care and use program of the institution if full-time; or the frequency and duration of visits if employed part-time or as a consultant.
  *Note:* If preferred, this information may be provided in a Table or additional Appendix.

Veterinarian's name: (b)(6) serves as the consultant veterinarian (CV) for the BVAMC. He has been employed as a consultant and appointed through the Medical Center Director's (MCD) office since 1986. He provides a minimum of one hour per week of consultation and care to the BVAMC ACUP and VMU. His responsibilities include:

-diagnoses, treats, and prevents diseases of the laboratory animals
-reviews the sick animal reports and prescribes treatment to be administered by the VMU personnel
-surgery and post-operative care
-pain management
-guidance on anesthesia and analgesia
-guidance on compliance with AVMA Euthanasia Guidelines
-participates with the ACUP Manager and PIs in preparing Standard Operating Procedures (SOPs) as needed
-provides advice on animal models and the proper use of animals in research
-assists investigators in filling out the Animal Component of Research Protocol (ACORP)
-Reviews all initial ACORPs, continuing reviews, third year reviews
-provides advice as necessary
-trains new personnel in research techniques
-assesses the competency of personnel to perform procedures as listed on protocols
-serves as consultant to Research Service
-is a voting member of the IACUC
-monitors the care and use of laboratory animals and participates in the review of all grant applications involving animal use forms
-available by telephone or pager when a problem arises

(b)(6) keeps up to date with current regulations and procedures by attending professional meetings and participating in continuing educational programs related to laboratory animal medicine. He is a member of AALAS and subscribes to the *Laboratory Animal Medicine Journal.*

Weekend, holiday, evening, and emergency coverage is provided on an ongoing basis by (b)(6) During the occasions when (b)(6) (b)(6) is unavailable, emergency coverage is provided by one of his associates at (b)(6)

**Monitoring Use and Care of Laboratory Animals**

(b)(6) monitors the use and care of laboratory animals in the

following ways:

1. Weekly consultation visits and meeting with the ACUP Manager to discuss ongoing projects, animal husbandry, and other issues that affect the animals housed at the BVAMC.
2. Meets with investigators and their staff to assess veterinary competencies.
3. Reviews the sick animal reports and prescribes treatment to be administered by the VMU personnel.

**ii.** List others (e.g., Principal Investigators, veterinarians serving as Principal Investigators, veterinary faculty/staff, technical staff, farm managers) who have a *direct role in the provision of veterinary care* and describe their responsibilities. The Organizational Chart(s) provided in **Appendix 4** must depict the reporting relationship between these individuals and the Attending Veterinarian.
*Note:* If preferred, this information may be provided in a Table or additional Appendix.

(b)(6) is the only veterinarian with a direct role in providing veterinary care for the BVAMC's VMU. (b)(6) directs PI's, VMU staff as needed in animal care and use.

**c. Interinstitutional Collaborations** [*Guide*, p. 15]
Describe processes for assigning animal care and use responsibility, animal ownership and IACUC/OB oversight responsibilities at off-site locations for interinstitutional collaborations.

Not applicable

**2. Personnel Management**

**a. Training, Education, and Continuing Educational Opportunities**
Describe *how* the IACUC/OB provides *oversight* and *evaluates the effectiveness* of training programs and the assessment of personnel competencies. Describe how training is documented.
*Note:* Do not include details about the training program, which should be

described in the following sections.

The IACUC is responsible for oversight and compliance with training for all individuals working with research animals at the VMU. Collaborative Institutional Training Initiative (CITI) animal and IACUC web-based training is required initially and then every 3 years for IACUC members, researchers, and their staff working with research animals. All VMU personnel are required to take CITI training every 3 years too.

CITI training is documented by the ACUP Manager who maintains training records of IACUC members, PIs, study personnel, and VMU personnel. The Research Administrative Office (RAO) documents VA and other required research training for the PIs and study personnel. The Chemical Safety Coordinator documents required safety training for the PIs and study personnel. PIs and study personnel with lapsed training requirements are not permitted to conduct their animal protocols. If all study personnel have lapsed training, the animal study is shut down temporarily until training has been completed and competencies checked by the ACUP Manager or the CV.

Training deficiencies are reported to the IACUC by the ACUP Manager or the RCO. The IACUC makes recommendations to the ACUP Manager and the AO/ACOS/R&D regarding animal training compliance. Gross misconduct or ignorance of animal training is reported to the R&D Committee who may take action with the researcher if compliance cannot be obtained in a timely manner.

The IACUC can appoint a study monitor for complex protocols to monitor and provide consultation and assessment. The RCO can also arrange with the PI and to observe to see if they are complying.

The IACUC reviews all ACORPs and ensures study personnel listed have experience and training to do the procedures listed. If study personnel don't have these then the ACORP describes how they will obtain necessary training. All competencies are assessed and documented on a form by the CV before the study starts. Study personnel competencies are only assessed at the beginning of a study or when a new procedure is

added.

It is the PI's responsibility to document study personnel training and submit it to the R&D administrative office. The ACUP Manager puts a copy of the veterinary competencies assessment in the study file.

Training program effectiveness is evaluated through continual monitoring of the PI and study personnel training and competency records kept by the ACUP Manager and RAO. Training program effectiveness is also evaluated by the continual monitoring of issues or incidents involving animals such as injuries or side effects from poor animal handling or surgery techniques. The monitoring is done by the ACUP Manager, VMU personnel, and study personnel and noted on animal records kept on animal cages and animal room doors. These records are reviewed by the ACUP Manager and brought to the attention of the CV and IACUC when deemed appropriate. The IACUC then recommends appropriate action to be taken by the CV and/or ACUP Manager.

**i. Veterinary and Other Professional Staff** [*Guide*, pp. 15-16]

For the Attending Veterinarian and other individuals having a direct role in providing veterinary medical care (veterinarians, other professional staff listed above, private practitioners, etc.), provide: name, credentials (including degrees), and a description of their qualifications, training, and continuing education opportunities.

*Note:* Please do not provide curriculum vitae of personnel; if preferred, this information may be presented in a Table or additional Appendix.

BVAMC Consulting Veterinarian: (b)(6)
Qualifications:
Private practice DVM for (b)(6)
BVAMC CV for the past (b)(6)
Qualifications/ Training: (b)(6) keeps up to date with current regulations and procedures by attending professional meetings and participating in continuing educational programs related to laboratory animal medicine. He is a member of AALAS, subscribes to the *Laboratory Animal Medicine* Journal and completes required annual web-based training.

ACUP Manager: (b)(6)
Qualifications: ACUP manager has worked as a veterinary technician for two years and as a VMU Manager for two years. She is responsible for the management of the facility and the supervision of the animal care technicians (ACTs). She spends approximately 65% of her time providing and overseeing animal care. She uses the Guide, VHA handbooks, our institution memoranda and policies, web-based information, and printed material such as books and journals to stay current with animal care and use information. When possible the ACUP Manager will attend pertinent conferences and trainings. (b)(6)
(b)(6)

**ii. Animal Care Personnel** [*Guide*, p. 16]

**1)** Indicate the number of animal care personnel.

Currently there are two employees, with one vacancy for a 0.7 position during the week.

**2)** Summarize their training, certification level and type, experience, and continuing education opportunities provided.
*Note*: If preferred, this information may be provided in a Table or additional Appendix.

Animal Care Technician, daily, 0.7 FTE: Vacant
Qualifications:
Animal Care Technician, weekends/holidays: (b)(6)
Qualifications: Experience working with animals in animal care at the (b)(6) uses the Guide, web-based information, VHA handbooks, institutional memoranda and policies to obtain current animal care and use information. She uses printed material such as books and journals. She may attend pertinent conferences and trainings when resources permit.

All employees are given ongoing training by the ACUP Manager to complete the required third year web-based training as well. Verbal communication, power point presentations, and on the job training

are utilized to keep the staff informed of current regulations and procedures.

**iii. The Research Team** [*Guide*, pp. 16-17; 115-116; 122; 124]

**1)** Describe the *general mechanisms* by which the institution or IACUC/OB ensures that research personnel have the necessary knowledge and expertise in the animal procedures proposed and the species used.

ACORPs

The PI must list the names, qualifications, training, and relevant experience of all study personnel involved in the study on the ACORP. ACORPs must detail how the study personnel who do not have experience will be trained. Prior to the ACORP approval by the IACUC, the biosafety form must be approved by the Subcommittee on Research Safety (SRS). The PI must address study personnel training, practices, and techniques required to ensure safety and procedures for dealing with accidents. The PI's signature on the form certifies that all study personnel will be aware of potential hazards and will receive instructions and training on the proper handling and use of chemical and biohazardous materials.

General laboratory and chemical safety training (Chemical Hygiene Plan)

General laboratory and chemical safety training is conducted prior to employment and then annually by the Chemical Safety Coordinator.

Specific Research Project Training

More specific chemical and hazardous agent and research project specific training is conducted by the PI with all new study personnel and with any existing study personnel if study protocols or hazards have changed.

Animal Care/Use and VMU Training

The ACUP Manager trains new study personnel in the following

regarding the VMU: security, occupational health and safety related to animals, animal allergens, animal ordering and shipping, animal rights activists and proper procedures, VMU SOPs, and general things like basic animal handling, proper identification of animals, etc.

The ACUP Manager ensures that VMU personnel receive training in proper procedures to work with the animals and related waste and equipment. She provides ongoing training in the form of verbal presentations, power point presentations, and printed handouts. Assistance for determining the need for additional training is provided by the CV, the Industrial Hygienist, the Infection Control Representative, and the Research Chemical Safety Coordinator.

The investigator is required to document training and experience of study personnel in their animal use form which must be approved by the IACUC prior to the initiation of the study.

IACUC Chair and ACUP Manager attend training presented at various conferences, such as IACUC Conference, and the PRIM&R Conference when resources permit.

**a)** Briefly describe the content of any required training.

CITI Animal Training

CITI training is a web based training that provides information essential for technicians, veterinarians, managers, IACUC members, study personnel, and PIs working with animals in a research or education setting. The training emphasizes the appropriate handling, care and use of animals. The courses are designed to help meet training mandates of regulatory agencies and improve knowledge in technical areas. The modules include the following: Working with the IACUC, Federal Mandates, Veterinary Consultation, USDA pain/distress categories, Endpoint Criteria, Surgery, Collecting Blood Samples, Personnel Training and Experience, Occupational Health and

Safety, Using Hazardous and Toxic Agents, Housing Social Animals, Animal Welfare Regulations and Standards, Prolonged Restraint, Euthanasia, Anesthetics, and Analgesics, Patient Care Areas for Animal Research, Explosive Agents, Controlled Substances, Making Changes to Protocols, and Reporting Misuse, Mistreatment, or Noncompliance.

PIs and study personnel must also take the CITI trainings for species-specific and procedure-specific courses applicable to their research.

Orientation/Annual Mandatory Training

Prior to employment at the BVAMC and regardless of compensation (VA employees, other funding sources, etc.) all study personnel receive mandatory annual training/orientation that includes information on the following:
Employee Health; Compliance and Business Integrity; Customer Service; Patient Safety and Patient Assisted Care Teams; Computer access, Paging, Phone system; Talent Management System (TMS); Community Affairs; Information Security and Privacy Policies; Safety and Emergency Management, Green Environment Management System (GEMS) and Hazardous Materials, Infection Control; Law Enforcement and Security.

VMU Training

Prior to commencing animal studies or employment, study personnel and VMU personnel including Without Compensation (WOC) appointment staff must take the following trainings annually: VA Information Security Awareness and Rules of Behavior, Privacy and HIPAA. Those working with human subjects must also take CITI Human Subjects Protection and Good Clinical Practices (every three years) and those working with animals must take the CITI animal trainings and the species- and procedure-specific trainings (every three years, VMU personnel must take these courses annually).

All PIs and study personnel working with animals receive the following educational training and materials from the ACUP Manager: Tour of the VMU describing the layout, copies of the animal research related institutional memoranda and policies, VHA Handbooks, a copy of the PHS Assurance for the BVAMC, the VMU SOP, the Chemical Hygiene Plan, and VMU security information and emergency exits for fire or other immediate hazards.

The VA Employee Health Nurse has new employee's complete surveys regarding health status and animal research activities the employee will be conducting. She provides information on the Employee Occupational Health and Safety Program and has the employee take appropriate immunizations, shots, or examinations.

Chemical/Hazardous Materials Training-Chemical Hygiene Plan

Prior to employment or working on research studies, study personnel receive general research physical, chemical, radiation, and hazardous agents safety trainings conducted by the Research Chemical Safety Coordinator. All study personnel receive a copy of the Chemical Hygiene Plan which includes our safety and emergency policies and a copy of the Emergency Operations Plan. The 60-minute initial training provides an overview of these policies and the plan.

Research Safety Training contains the following information: Biosafety and Biosecurity Program, Control of Chemical and Hazardous Agents, Safety and Responsible Conduct of Personnel Engaged in Research, Working with Radioactive Isotopes, Hazardous Drug Safety Program and Hazardous Pharmaceuticals List, Guidelines for Research Chemical Waste Disposal, Research Biosafety Subcommittee, Research Emergency Operations and Response Plan, Infection Control, Occupational Health and Safety, Waste Management, Chemical Spill Procedures, Hazard Communication, Exposure Plan,

Chemical Storage Guidelines, Proper and Safe Handling of Compressed Gas Cylinders, Systems Failure and Basic Staff Response Guidelines, Back Tips for Healthcare Workers, and Employee's Emergency Treatment Form.

Animal Study Competencies
All personnel working with animals must have their competencies assessed to perform the procedures listed in the ACORP. These assessments are conducted by the CV and/or the PI prior to starting their studies.

Specific Study Training
Training specific to the study is conducted by the research project PI and may take anywhere from 30 minutes to several hours depending on the study and chemical and hazardous agents involved.

**b)** Describe the timing of training requirements relative to the commencement of work.

All training is to be completed prior to the commencement of work.

**c)** Describe continuing education opportunities offered.

The following continuing education opportunities exist for VMU and study personnel:
-Additional modules in CITI
-IACUC Conferences and materials provided by (b)(6) (b)(6)
-Information on the Internet
-Scientific journals and articles

**2)** Describe the process(es) to ensure surgical and related procedures are performed by qualified and trained personnel, including:

- who determines that personnel are qualified and trained for surgical procedures
- the roles that the Attending Veterinarian and IACUC/OB have in this determination [*Guide*, pp. 115-116]

The following processes are in place to ensure surgical and related procedures are performed by qualified and trained personnel.

Prior to any study commencing, the ACORP is reviewed and approved by the IACUC. The PI must list the names, qualifications, training, and relevant experience of all study personnel involved in the study on the ACORP. ACORPs must detail how the study personnel who do not have experience will be trained. The PI must address study personnel training, practices, and techniques required to ensure safety and procedures for dealing with accidents. The PI's signature on the form certifies that all study personnel will be aware of potential hazards and will receive instructions and training on the proper handling and use of chemical and biohazardous materials.

The CV provides consultation to the PI and reviews the ACORP prior to it being submitted to the IACUC.

All personnel working with animals must have their competencies assessed to perform the procedures listed in the ACORP. These assessments are conducted by the CV and/or the PI prior to starting their studies.

Unanticipated outcomes should be discussed with the CV and modification processes will be followed to obtain IACUC approval. Communication between study personnel, PIs, VMU personnel, CV, and the IACUC is essential.

**3)** Describe the training and experience required to perform anesthesia. [*Guide*, p. 122]

PI or study personnel performing anesthesia must document

training and experience on the ACORP before submitting the form to the IACUC for approval. If training is needed, it is directed and supervised by the CV. The CV and/or PI perform a veterinary competency assessment of study personnel prior to the start of the study to ensure personnel are proficient to perform the approved ACORP procedures.

4) Describe how the proficiency of personnel conducting euthanasia is ensured (especially physical methods of euthanasia). [*Guide*, p. 124]

The proficiency of study personnel conducting euthanasia is ensured through the training, observation, and assessment of the veterinary competency by (b)(6) (the BVAMC CV) for each study personnel conducting euthanasia.

**b. Occupational Health and Safety of Personnel** [*Guide*, pp. 17-23]

**i. Institutional Oversight** [*Guide*, pp. 17-19]

1) List the institutional entities (units, departments, personnel, *etc.*) that are involved in the planning, oversight, and operation of the institutional occupational health and safety program related to animal care and use (e.g., office(s) of environmental health, institutional health services or clinics (*including contracted health services*), industrial hygienists, Institutional Biosafety Committee(s) and/or Officer(s), Radiation Safety Committee(s) and/or Officer(s).

- Include a brief description of their responsibilities and qualifications.
- If contracted services are used, also include their location (e.g., remote offices to which personnel must report).

The BVAMC's Occupational Health and Safety Program (OHSP) for personnel with laboratory animal contact is operated and monitored by the BVAMC Employee Health Office in consultation with the hospital Safety Office and the Infection Control Office. All personnel who work in the laboratory animal facility or who have contact with laboratory animals or animal tissue are offered an opportunity to participate in the program. Personnel included are

those individuals who have direct contact with animals (live or euthanatized), their viable tissues, body fluids, or wastes. This includes all VMU personnel, study personnel, and PIs. At risk personnel in Facility Management Services (FMS) and Police Services are included as well as the CV and all IACUC members. Those PIs and study personnel from affiliated universities are also enrolled in the VA's program, but may decline enrollment in writing if they are enrolled in their university's OHSP.

The BVAMC OHSP includes pre-employment medical examinations, tuberculosis screenings (skin tests, X-ray), tetanus immunization, special immunizations as needed for specific research projects, and screening programs. Counseling on occupational hazards is provided by the PI, ACUP Manager, and Employee Health Office. Injuries (animal bites, needle sticks, etc.) and potentially work-related illnesses or injuries are documented in the Automated Safety Incident Surveillance and Tracking System (ASISTS). All ASISTS reports are reviewed and evaluated by the Industrial Hygienist and Human Resources.

**2)** Describe methods to identify work-related hazards and the processes used to evaluate the significance of those hazards in the context of duties and tasks. Describe both common approaches and differences, if applicable, for categories of personnel such as, but not limited to, researchers, veterinarians, husbandry staff, cage-washing staff, students, housekeeping, physical plant staff, security personnel, IACUC/OB members (including non-affiliated members), contractors, visitors, etc. [*Guide*, pp. 18-19; see also Chapters 2 and 3 in Occupational Health and Safety in the Care and Use of Research Animals, NRC 1997.].

The initial identifying of work-related risks and evaluation of their significance begins with the PI. Hazardous agents, all risks and their significance are identified by the PI on the initial study "Research Protocol Safety Survey" (Biosafety Form) and on the ACORP. And each is reviewed by their corresponding subcommittees, Subcommittee on Research Safety (SRS) and the IACUC. Membership of the SRS includes representatives from the

Industrial Hygiene/Safety Office, Chemical Safety Coordinator, Infection Control representatives, the American Federation of Government Employees (AFGE) representative, and other PIs working at the BVAMC. The SRS reviews the biosafety form for hazardous agents, safety issues and other risks listed and assesses each risk and the significance of the risks. Subcommittee members may contact the PI to ask clarifying questions and make recommendations to improve the safety of the protocol and study staff. Risk assessments are conducted and evaluated each year during study annual reviews therefore ensuring any changes are reported and discussed with the SRS. The same process occurs with the ACORP and the IACUC.
Each laboratory has a copy of the Research Lab Safety Plan and the Chemical Hygiene Plan which also contains information on laboratory hazards and how to reduce or eliminate them. Additional Standard Operating Procedures (SOPs) are prepared as needed.

The institutional OHSP in consultation with the station Safety Office and Infection Control Office identifies potential hazards in the work environment at least annually in association with the Environment of Care (EOC) teams. They inspect all work and laboratory spaces, including the VMU) to identify potential hazards and safety compliance.

In addition to the EOC, we also participate in the Annual Workplace Evaluation (AWE) conducted by our Veterans Integrated System Network (VISN) 20. Their specialists in chemicals, biohazards, and physical hazards inspect the animal facility and report back on any problems. Action plans are developed and carried out by the ACUP Manager and supported by the AO and IACUC.

**3)** Describe methods and frequency of reassessing work-related hazards.

As mentioned in b.i.2, methods for assessing and reassessing work-

related hazards are conducted by the EOC and the AWE teams. They primarily conduct walk throughs and talk with the PIs and research staff about what and how they are doing protocols. Through observation and asking questions at least annually, each group reassesses work-related hazards. Hazards identified are collected by the teams and a report is sent back to the AO. The report is shared with the SRS, the Chemical Safety Coordinator, the VMU manager and the Associate Chief of Staff for Research. (ACOS). For the VMU, the VMU manager works with those necessary to review the report and develop and carry out an action plan to correct, minimize or eliminate the hazard. Because these data and reports are collection, potential trends for hazards can be identified from reviewing past reports and analyzing any trends. and how they are doing.

The methods mention above are primarily annual but assessing and reassessing work-related hazards is an ongoing process. The ACUP manager implements a team concept that encourages all personnel involved in research to take part in developing safety measures to manage risk. Individuals are encouraged to be familiar with policies and procedures in the VMU while constantly accessing and developing safety concepts to keep all parties safe from potential risk. Safety specialists on all levels are utilized daily when using the team concept, ensuring safety hazards are kept to a minimum.

**4)** Describe institutional programs or methods used to track and evaluate safety-related workplace incidents, including injuries, exposures, accidents, etc. Include the frequency of such assessments. [*Guide*, pp. 18-19]

Reporting exposure to hazards, work place injuries, etc. are conducted using ASISTS. This reporting system is readily available on VA computers through the VA computer Application Manager. All incidents must be reported within 24 hours to the AO and/or supervisor. After hours the employee may go to the Emergency Room or during normal tour of duty hours they can be seen by the Employee Health Office.

It is the responsibility of the PI/supervisor to complete the ASISTS form with/for their staff. Reports of exposure to hazards and work place injuries are reported to the Employee Health Office or the Emergency Room Physician, the employee's supervisor, and the SRS. Potential hazards should be reported to the ACUP Manager, PI, and/or Industrial Hygienist to determine what actions need to be taken.

**ii. Standard Working Conditions and Baseline Precautions**

The following section pertains to the Occupational Health and Safety Program for all personnel associated with the animal care and use program. Specific information regarding the use of hazardous agents is included in ***subsection iii*** below.

**1) Medical Evaluation and Preventive Medicine for Personnel** [*Guide*, pp. 22-23] *Note:* Include blank forms used for individual health assessment as **Appendix 6.**

**a)** Describe who (e.g., personnel assigned to job/task categories in I.A.2.b.i.2) above) receives personal medical evaluation as a component of individual risk assessment. Describe who are ***not*** included and/or exempted from personal medical evaluation. *Note:* Do not include the names of personnel.

The BVAMC's Occupational Health and Safety Program (OHSP) for personnel with laboratory animal contact is operated and monitored by the BVAMC Employee Health Office. All personnel who work in the laboratory animal facility or who have contact with laboratory animals or animal tissue are offered an opportunity to participate in the program. Personnel included are those individuals who have direct contact with animals (live or euthanatized), their viable tissues, body fluids, or wastes. This includes all VMU personnel, study personnel, and PIs. At risk personnel in Facility Management Services and Police Services are included as well as the CV and all IACUC members. Those PIs and study personnel from affiliated universities are also enrolled in the VA's program, but may decline enrollment in writing if they are enrolled in their university's OHSP. All

personnel are included in this program.

**b)** Describe provisions for allowing an individual (following completion of individual health and job-related risk assessments) to decline participation in all or part(s) of subsequently available medical and preventive medicine components of the institutional program, e.g., vaccinations, physical examinations, respiratory protection, as applicable. Provide an estimate (percentage) of personnel associated with the animal care and use program that have declined participation in the medical evaluation program.
*Note: Do not include names of the personnel*

All individuals declining participation in the OSHP must document the declination in writing on the OSHP questionnaires. Approximately 50% of the laboratory (animal and nonanimal) researchers decline participation in writing.

**c)** Describe provisions for assuring confidentiality of medical information.

The Department of Veterans Affairs' (VA) Veterans Health Administration (VHA) is required by law to maintain the privacy of protected health information. VHA is also required to abide by the terms of its privacy policies.
Paper documents that contain protected health and medical information or individually identified information are kept in locked file cabinets in locked office in either the Chemical Safety Coordinators office until they can be transferred to the Employee Health Office where they are also locked in a file cabinet in a locked office. If documents containing privileged information were to be used, these would be on a VA computer on the VA encrypted network on the S drive in a locked folder with permission limited to those who need to know that information.

**d)** Describe safety considerations for individuals with incidental exposure to animal care and use (e.g., contractors, personnel working in open laboratories).

Police and FMS employees are trained through the Talent

Management System (TMS) system. This computerized system consists of many training courses which can be assigned to specific individuals. For example, those individuals who work with hazardous materials, regardless of where they work, are assigned the training course on hazardous materials. This training covers a variety of information including door signage, hazardous materials, and PPE protocols. Contractors needing to do work in the VMU are provided information on the hazardous or potentially hazardous materials or agents in the building and told not to touch anything they don't need to. They are provided personal protective equipment and are continually escorted in the VMU facility by a VMU staff member due to the potential risks and hazards inherent in the building.

**e)** Describe general features of the medical evaluation and preventive medicine programs, within the context of work duties, including:

- pre-employment/pre-assignment health evaluation,
- medical evaluations (including periodicity),
- diagnostic tests (e.g., for tuberculosis),
- precautions for working with potentially hazardous species (e.g., nonhuman primates, sheep, venomous species)
- immunization programs, and
- procedures for communicating health related issues.

The pre-employment/pre-assignment health evaluation, for the OHSP features the following for new employees (prior to employment): questionnaires regarding medical history, current vaccinations, allergen exposure history, a tuberculosis test and a blood screening. For returning employees, the OSHP requires questionnaires regarding medical history, current vaccinations, allergen exposure history, and optional blood screening.
Any employee wishing to decline participation may do so in writing.
Medical evaluations and diagnostic testing would be conducted periodically as determined by the Employee Health Office for example when using cancer therapies or when specific badges to monitor gases or other agents is identified on the badge.
Precautions for working with potentially hazardous species is

addressed by using personal protective equipment (PPE) and any vaccinations for the employee(s) to provide immunologic protection.
Laboratory employees are required to document tetanus immunizations and annual flu immunizations. Both are available from the Employee Health Office if needed.
Procedures to communicate health-related issues is discussed within the Infection Control team, which includes the Infection Control Officer and the ACOS of Research. When communication is warranted, the Infection Control Officer works with the Public Affairs office to communicate within the institution via email and flyers. If communication is needed outside or external to the VA, that communication is reported to the Medical Center Director. He then works with the Public Affairs office and their communication team to report any needed communication to the public via various social media routes.

**f)** Describe any other entities that provide medical services (e.g., emergency care, after-hours care, special medical evaluation, contracted services). Include a brief description of their credentials and/or qualifications, and how these entities remain knowledgeable about animal- or institution-related hazards and risks.

The Boise VA Medical Center is staffed 24 hours a day, seven days a week by licensed health care providers. Licensing is verified by the Credential Office in Human Resources. Our health care professionals remain knowledgeable about animal and institutional-related hazards and risks by taking required trainings annually and documented in the TMS database. Professional trainings and hospital rounds are conducted on a regular basis. Grand Rounds are conducted weekly. The Safety Office identified emerging issues where training is needed. The training is sent to all employees or conducted in small groups and documented in the TMS database.

**2) Personnel Training Regarding Occupational Health and Safety**
[*Guide*, p. 20]

Describe general educational program(s) to inform personnel about:

- allergies,
- zoonoses,
- personal hygiene,
- physical injuries in animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural animals),
- other considerations regarding occupational health and safety.

Include in the description a summary of the topics covered, including:

- Entities responsible for providing the training
- Frequency of training or refresher training

*Note*: Do not include special or agent-specific training for personnel exposed to experiment-related hazardous agents; this will be provided in **Section iii.3** below.

All study personnel receive annual training in infection control and chemical hygiene by the Chemical Safety and Training Coordinator. They are assigned similar training in TMS. SOPs and the approved ACORP are distributed to all study personnel involved with their research project. All study personnel receive SDS training. Pertinent SDS are available on the web-based VA Program Manager SDS site. Study personnel working with animals exposed to hazardous agents are trained in proper procedures by the PI and competencies assessed by the CV. Study personnel are also trained by the ACUP Manager in proper procedures to work with the animals and related waste and equipment. During her training she covers allergies, zoonoses, and personal hygiene topics as listed below.

**Personal Protective Equipment (PPE)/Work Clothing Provided**
Personnel with potential exposure to hazardous agents are provided with protective equipment appropriate to the agents. Any specialized equipment needed for VMU personnel can be obtained through the Industrial Hygienist. Protective equipment/work clothing provided includes: Scrubs, laboratory coats, disposable gloves, shoe covers,

safety glasses, face shields, goggles, N100 and N95 particulate respirators, face masks, and ear protection. Scrubs and laboratory coats are picked up twice weekly from the locker rooms, laundered by the medical center laundry department, and returned the following week.

We have dedicated bedding disposal station for hazardous agents. Bedding disposal dedicated to hazardous agent cage waste located between four small animal housing rooms (rooms 123, 124, 125, 126). Two doors separate the area from the main facility corridor.

Utilization of bedding disposal stations and particulate respirators is not optional. Exposure to rodent dander has been documented to cause allergic reactions in 50% of persons.

**Provisions for Washing Hands, Changing Clothes, Wearing Work Clothes Outside Facility**

Change facilities (locker/restroom with shower) are provided for both male and female workers in the VMU. Scrubs and lab coats are to be worn only while in the VMU and changed before leaving. Sinks, medicated soap, antiseptic gel, and paper towels are placed in convenient locations throughout the facility, especially in or near animal and surgery rooms. Soiled or contaminated work clothes must be left in the facility.

**Eating, Drinking, and Smoking Policies**

Eating, drinking, or smoking is not permitted in any animal room or on VA property. The ACUP Manager's office in (b)(6) (b)(6) are the only designated eating areas in the VMU both of which are in the administration area which is separate from the animal portion of the facility. Workers may go to the Medical Center cafeteria on breaks. Medical Center policy prohibits smoking in any building. Noncompliance of study personnel with the above rules and policies are immediately warned and reminded of the rules and policies. Continued noncompliance is reported to their supervisor. Retraining and/or disciplinary action may be taken for continued noncompliance

with these safety issues.

**Medical Evaluation and Preventive Medicine for Personnel**
**Occupational Health and Safety Program (OHSP)**
The OHSP for personnel with laboratory animal contact is operated and monitored by the Boise VAMC Employee Health Service. All VMU and study personnel who work in the laboratory animal facility or who have contact with laboratory animals or animal tissue must participate in the program. Personnel included are those individuals who have direct contact with animals (live or euthanatized), their viable tissues, body fluids, or wastes. At risk personnel in Facility Management Services (FMS) and the Police Service are included as well as the CV and all IACUC members. The OHSP includes pre-employment medical examinations, tuberculosis screenings (skin tests, X-ray), tetanus immunization, special immunizations as needed for specific research projects, and screening programs. Counseling on occupational hazards is provided by the PI, ACUP Manager, and Employee Health Service. Injuries (animal bites, needle sticks, etc.) and potentially work-related illnesses or injuries are evaluated by Employee Health Service. Oversight of the OSHP as it relates to personnel working with animals is conducted by the IACUC and the SRS.

**3) Personal Hygiene** [*Guide*, p. 20; *Ag Guide* pp. 4-5]

**a)** List routine personal protective equipment and work clothing provided and/or required for animal care personnel, research and technical staff, farm employees, etc.

Personnel with potential exposure to hazardous agents are provided with protective equipment appropriate to the agents. Protective equipment/work clothing provided includes: Scrubs, laboratory coats, disposable gloves, gloves for working with liquid nitrogen, shoe covers, safety glasses, face shields, goggles, N100 and N95 particulate respirators, and face masks. Additional or specialized PPE may be obtained from the Industrial Hygienist.

**b)** Describe arrangements for laundering work clothing.

Scrubs and laboratory coats are picked up twice weekly from the locker rooms, laundered by the medical center laundry department, and returned the following week.

**c)** Describe provisions and expected practices for washing hands, showering, and changing clothes, including instances where work clothes may be worn outside the animal facility.

Change facilities (lockers/restrooms with shower) are provided for both male and female workers in the VMU. Scrubs and lab coats are worn only while in the VMU and changed before leaving. Sinks, medicated soap, gel and paper towels are in convenient locations throughout the facility and in each animal and procedure room and surgery area. Soiled or contaminated work clothes must be left in the facility.

**d)** Describe policies regarding eating, drinking, and smoking in animal facilities.

VMU and SRS policies prohibit eating, drinking, or smoking in any animal room, procedure room or laboratory space. Building (b)(6) (b)(6) are the only designated eating areas in the VMU. (b)(6) (b)(6) Workers may go to the Medical Center cafeteria on breaks. Medical Center Memorandum 00-13-14, Smoke-Free Policy, prohibits smoking in any building.

**4) Standard Personnel Protection** [*Guide*, pp. 21-22]

**a)** Describe facility design features, equipment and procedures employed to reduce potential for physical injury inherent to animal facilities (e.g., noisy areas, large quantities of chemicals such as disinfectants, ergonomics) or species used (e.g., nonhuman primates, agricultural

animals).

Rodents are the only animals utilized at the VMU. Special stress relieving mats are utilized in locations where personnel may be standing for extended periods of time. The VMU utilizes small quantities of disinfectants for use. These are housed in metal rolling cabinets and kept inside plastic bins to ensure containment of any leaks.

**b)** Describe likely sources of allergens and facility design features, equipment, and procedures employed to reduce the potential for developing Laboratory Animal Allergies (LAA).

Animal rooms are isolated and separate from general purpose areas. Personnel are trained in keeping doors closed to animal rooms. Air exiting animal rooms are filtered to contain allergens leaving the building. Fresh air from outside the building is supplied to the entire facility to eliminate the recycling of possible allergens.

**c)** Describe likely sources of zoonoses and facility design features, equipment, and procedures employed to reduce potential exposure to zoonoses.

Only rodents are housed at the VMU. Rooms are supplied with fresh air from outside and not recycled. Personnel are trained in using PPE to ensure containment of contaminants. Personnel are provided Scrubs, laboratory coats, disposable gloves, shoe covers, safety glasses, face shields, goggles, N100 and N95 particulate respirators, and face masks. Scrubs and laboratory coats are picked up twice weekly from the locker rooms, laundered by the medical center laundry department, and returned the following week. When coats are dirty they are placed promptly in the laundry. Personnel change gloves between rooms and between handling cages, racks, and shelves as needed. Equipment is sanitized between rooms or exclusive to only one room to avoid cross contamination.

**d)** Describe the procedures for the maintenance of protective equipment and how its function is periodically assessed.

PPE equipment is evaluated daily. Specialized respirators are evaluated every six months for maintenance and cleaned as needed. Specialized respirator care may be dependent upon use of the mask. Masks are assigned to individual personnel after certification by the Industrial Hygienist. Special sanitizing wipes are used to clean the masks after use.

**e)** Respiratory Protection

**i)** Describe situations where respiratory protective equipment is available or required, such as cage washing facilities, feedmills, etc.

Respiratory equipment is always available to personnel during the process of cleaning cages. PPE equipment is utilized during sanitization of treated cages.

**ii)** Describe programs of medical clearance, fit-testing, and training in the proper use and maintenance of respirators.

The Respirator Program is managed by the Industrial Hygienist. She is certified to evaluate medical clearance to use a respirator. The Hygienist will fit test each individual and train personnel to care for and utilize the respirators safely.

**iii)** Describe how such respiratory protective equipment is selected and its function periodically assessed.

Any hazardous agent requiring a respirator includes training and enrollment in the Respirator Program by the Industrial Hygienist. The Hygienist evaluates and trains individuals annually. She evaluates face size for fit, use of respirator, and conditions.

**f)** Heavy Equipment and Motorized Vehicles

**i)** Provide a general list of the types of cage-processing equipment used, such as rack/cage washers, tunnel washers, robotics, and bulk autoclaves. Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
*Note:* Details of specific equipment installed in animal facility(ies) are to be provided in **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

The VMU (Veterinary Medical Unit) has one cage washer that is utilized in the cleaning of caging equipment. The Cage washer is a Steris model with signage inside the unit as well as two emergency ways to stop the unit. The unit has a pull cord to stop the unit and an explosion door release. Training for this unit is overseen by the VMU Manager personally. Detailed instructions are given to personnel prior to using the machine. Training is comprised of power-point and verbal-hands-on training. A critique method of training is utilized and employees discuss what they have learned at the end of each training day. A sign-off sheet is gone over at the same time to ensure all points of safety and use are covered.

**ii)** List other heavy equipment such as scrapers, tractors, and farm machinery (manufacturer name, model numbers, etc. are not necessary). Describe training programs, informational signage, and other program policies designed to ensure personnel safety when working with such equipment.
*Note:* If preferred, this information may be provided in a Table or additional Appendix.

None-NA

**iii)** If motorized vehicles are used for animal transport, describe how the driver is protected from exposure to hazards such as allergens or zoonoses and decontamination methods employed. Also describe instances where vehicles may be shared between animal and passenger transport.

NA

**g)** Describe safety procedures for using medical gases and volatile anesthetics, including how waste anesthetic gases are scavenged.

Animal surgery is performed only in areas appropriate for the type of surgery and species being used. Ordinary research laboratories or small animal procedure rooms can be used for non-sterile, terminal procedures in small animal species. Three core small animal procedure rooms in (b)(6) and a core support laboratory area in the VMU are available for use in various projects by appointment.

The tabletop rodent inhalation anesthesia systems use Isoflurane and activated charcoal absorption filters to remove waste anesthetic gases.

### iii. Animal Experimentation Involving Hazards [*Guide*, pp. 20-21]

**1)** List, according to each of the categories noted below, hazardous or potentially hazardous agents currently approved to be used in animals that are or will be maintained for more than a few hours following exposure. If the hazardous agent cannot be listed by name for security/proprietary reasons, identify it by the general category of agent and level of hazard. *Note:* If preferred, this information may be provided in a Table or additional Appendix.

**a)** Biological agents, *noting hazard level* (CDC Biohazard Level, Directive 93/88 EEC, CDC or USDA/DHHS Select Agent, etc.). Examples may include bacteria, viruses, viral vectors, parasites, human-origin tissues, etc.

**Biologic agents**

| Name | BSL Level |
|---|---|
| Clostridium sordellii | 2 |
| Clostridium difficile | 2 |
| Clostridium septicum | 2 |
| Group A Streptococcus | 2 |

| | | |
|---|---|---|
| Streptococcus pyogenes, | | |
| strain ATCC 12384 | and | 2 |
| strain 88/003 and strain 96/004 | | 2 |
| Staphylococcus aureus | | 2 |
| NSCLC A549 | | 2 |
| H1N1 A/PR/8/34 | | 2 |
| MRSA (USA300, LAC-wt) | | 2 |

b) Chemical agents, *noting general category* of hazard (toxicant, toxin, irritant, carcinogen, etc.). Examples may include streptozotocin, BrdU, anti-neoplastic drugs, formalin, etc.

# Chemical Agents

| Name | Hazard Level/HMIS Category |
|---|---|
| 5-Bromo-2-deoxy-uridine (BrdU) | 1-Irritant, toxic |
| Bleach | 1-Corrosive |
| Buprenorphine | 3-Irritant, Teratogen |
| Ceftriaxone | 2-Irritant, Sensitizer |
| Dithiothreitol | 1-Irritant |
| DMSO | 2-Irritant, Mutagen |
| Doxycycline hydrate | 2-Irritant |
| Ethanol | 2-Irritant<br>3-Flammable |
| Ethidium bromide | 3-Mutagen<br>2-Irritant |
| Formaldehyde | 3-Carcinogen, Corrosive, Allergen |
| Guanidine thiocyanate | 3-Toxic |
| Isoflurane | 2-Irritant (eye, skin)<br>Reproductive toxicity, organ damage with prolonged or repeated exposure |
| Ketamine | 2-Irritant |
| Ketorolac tromethamine | 2-Toxic(oral), Irritant |
| Toradol | 1-Irritant |

| | |
|---|---|
| Linezolid | 1-Irritant, toxic |
| Methanol | 2-Irritant (eyes, respiratory tract) |
| Nembutal | 1-Irritant<br>2-Health<br>2-Mutagen |
| Paraformaldehyde | 2-Irritant(skin), Toxic |
| siRNA(Ambion) | 1-Toxic |
| Sodium dodecyl sulfate | 2-Health<br>3-Flammabiity<br>3-Reactivity, Irritant (skin, eye) Toxic (oral, inhalation, skin, aquatic)<br>Flammable |
| TEMED | 3-Corrosive (skin, eye)<br>3-Flammable, Toxic (oral, inhalation) |
| Vancomycin | 2-Irritant(skin), Allergen |

**c)** Physical agents (radiation, UV light, magnetic fields, lasers, noise, etc.).

Not Applicable – BVAMC does not use any of these physical agents.

**2) Experiment-Related Hazard Use** [*Guide*, pp. 18-19; See also Chapters 2 and 3 in *Occupational Health and Safety in the Care and Use of Research Animals*, NRC 1997].
*Note:* Written policies and standard operating procedures (SOPs) governing experimentation with hazardous biological, chemical, and physical agents should be available during the site visit.

**a)** Describe the process used to identify and evaluate experimental hazards. Describe or identify the institutional entity(ies) responsible for ensuring appropriate safety review prior to study initiation.

The process used to identify and evaluate experimental hazards consists of the PI identifying the experiment hazardous agents during the initial review of the project on the biosafety risk assessment called the "Research Protocol Safety Survey" (Biosafety Form).
The completed form is reviewed by the Subcommittee on Research Safety (SRS). The membership of this committee

includes the station Industrial Hygienist (IH), the Chemical Safety Coordinator, and Infection Control representatives and other PIs. The group reviews the completed form for the hazardous agents listed and the methods used to use it in the project safely. The Research Laboratory Safety Manual and Chemical Hygiene Plan in each laboratory contains information on lab and experiment hazards and methods for safe use, clean up and disposal.

This same process is used with the PI identifying experiment related hazardous agents for the initial review of the ACORP by the IACUC.

If the description of the experiment hazards mitigation is insufficient during either of these committee reviews, the protocol is returned to the PI and a discussion is had between the PI and committee members to make adjustments to the protocol to mitigate the hazardous agents. The committees review and approve the change.

With the study approved for hazardous agent provisions by the SRS and the IACUC, the protocol goes to the R&D Committee for a final initial review. Once the committee reviews the protocol and the responses from the SRS and IACUC, the ACOS/R&D writes a memo to the PI telling him his study has been approved and he may now start his experiments.

**b)** Describe how risks of these hazards are assessed and how procedures are developed to manage the risks. Identify the institutional entity(ies) responsible for reviewing and implementing appropriate safety or containment procedures.

The process for assessing the project hazard risks is included in the two committee reviews described above in section 2.a. Each of these forms identify the risks of the hazards involved. Risk is assessed by the PI and the committee by assessing the nature and severity of the hazard to the individuals involved, the degree of exposure to the risk and the route of exposure as described by the PI on the forms. The PI also describes the methods that will be

used in managing and monitoring the health and safety of personnel involved in the research.
Procedures developed to manage the risk include the Chemical Hygiene Plan and the Research Laboratory Safety Manual outline and describe how to manage the hazards. This manual is a compilation of information from various chemical and biological resources. This manual was written by the research staff and reviewed and approved by the SRS. The manual contains many SOPs for managing laboratory/experiment hazards.

Another process to manage hazard risks is to ensuring proper training for staff. All lab staff must be trained to identify and manage these hazards. Staff take annual computer trainings for the following areas: infection control (hand washing), using chemical and hazardous agents, handling different animal species, and protection and prevention of study personnel from exposure to allergens and zoonotic diseases. Training compliance is monitored by the PI and the Research Admin office.

Additional processes or procedures used in the VMU to manage risk include:
-Annual inspections from the hospital's Environment of Care Committee (EOCC). They conduct walk-throughs to identify potential hazards. A deficiency report is issued if hazards are identified and the PI must identify a plan to correct the deficiency and the timeline.
-All personnel working with these agents must be enrolled in the VA Occupational Health and Safety Program and placed on the appropriate screening programs.
-Knowledge and use of safety data sheets (SDS).
-There are no animal protocols utilizing radioisotopes at this facility.
-Personal protective equipment (PPE) such as lab coats, scrubs, gloves, masks, respirators, face shields, etc. are also used to control exposure of chemical and hazardous agents to VMU and study personnel. Special protective equipment such as chainmail gloves, decapicones, and rodent restrainers are available for use to

help reduce the risk of animal bites.
-Evaluating potential workplace hazards and injuries is also done by the station Industrial Hygienist working with the PI and study personnel. With the Industrial Hygienist on the SRS, experiment hazards are identified and procedures to manage the hazards are work on together by the IH and the PI and staff.

**c)** Describe the handling, storage, method and frequency of disposal, and final disposal location for hazardous wastes, including infectious, toxic, radioactive carcasses, bedding, cages, medical sharps, and glass.

Infectious or hazardous waste produced in the animal facility (b)(6) is placed in red double bags and placed in locked red biohazard carts for pick-up by FMS as needed for removal by the outside contractor, autoclaved and then disposed of in the landfill.

Waste containing antineoplastic agents is put in double yellow bags, placed in yellow containers inside locked red biohazard cart for removal by FMS as needed for incineration by the outside contractor.

Bacterial culture plates and associated waste will be autoclaved before being placed in blue biohazard bags for Sanipak disposal.

Full sharps containers are removed by FMS and autoclaved by the contractor before disposal in the landfill.

Hazardous or infectious agent exposed rodent carcasses are double bagged in red bags and place in locked red biohazard carts labeled Biohazardous and picked up by FMS two times per week. It is picked up by an outside contractor who autoclaves it and disposes of contents in the landfill.

**d)** Describe aspects of the medical evaluation and preventive health program specifically for personnel potentially exposed to hazardous agents.

The BVAMC OHSP includes pre-employment medical examinations, tuberculosis screenings (skin tests, X-ray), tetanus immunization, special immunizations as needed for specific research projects, and screening programs. Counseling on occupational hazards is provided by the PI, ACUP Manager, and Employee Health Office. Injuries (animal bites, needle sticks, etc.) and potentially work-related illnesses or injuries are documented in ASISTS and evaluated by Employee Health and Safety Offices. Our Research Laboratory Safety Manual also contains information for staff on what to do if they come in contact with various hazards.

3) **Hazardous Agent Training for Personnel** [*Guide*, p. 20]
Describe special qualifications and training of staff involved with the use of hazardous agents in animals.

Individuals who train research staff that use hazardous agents include the CV, PI, Industrial Hygienist and the VMU Manager. Their qualifications to conduct these trainings include academic work earning professional degrees in veterinary medicine, PhD programs in Microbiology, Immunology and other biological sciences, and certifications in industrial hygiene and laboratory animal technician. In addition to the academic credentials, all have a minimum of 10+ years working with such hazardous agents with animals. The ACORP lists who the trainers and students for each protocol. That way ACORP reviewers can assure qualified personnel conduct the trainings.

All staff must complete the CITI on-line training for IACUC and the specific species they will work with. After each course, the staffer must complete an exam and receive a certificate of completion. This training is monitored by the ACUP Manager and the Research Admin office.

4) **Facilities, Equipment and Monitoring** [*Guide*, pp. 19-20]

a) Describe locations, rooms, or facilities used to house animals exposed to hazardous agents. Identify each facility according to the hazard(s) and

containment levels (if appropriate).
*Note:* If preferred, information may be provided in a Table or additional Appendix.

The Boise VMU is a BSL- 2 facility. The VMU is housed in (b)(6) research facility on campus.

**b)** Describe circumstances and conditions where animals are housed in rooms outside of dedicated containment facilities (i.e., in standard animal holding rooms). Include practices and procedures used to ensure hazard containment.

This practice is not conducted at the Boise VAMC.

**c)** Describe special equipment related to hazard containment; include methods, frequency, and entity(ies) responsible for assessing proper function of such equipment.

Management and safety containment practices for each class of hazardous agent are performed by trained study personnel. Appropriate PPE are used and hazardous agent storage is conducted according to the appropriate SDS. Chemical agent inventories are updated semi-annually and reviewed by the Chemical Safety Coordinator and the Industrial Hygienist. Annual environment of care rounds for safety are conducted as part of the management and safety practices for using hazardous agents.

Fire extinguishers are located by entry and exit doors and maintained by the Safety Office and checked monthly. Spill kits are labeled and located in the dirty cage room in the VMU. These are maintained by the VMU Manager with assistance from the Safety Office. Chemical hazards are placed in double containers to prevent spillage. Chemicals are also stored in in flammable cabinets – maintained by the Research Service and checked annually by the Safety Office.

Sharps containers are supplied by Housekeeping, maintained by each laboratory staff member and disposed of by Housekeeping.

**d)** Describe the husbandry practices in place to ensure personnel safety, including any additional personnel protective equipment used when work assignment involves hazardous agents.

PIs provide specific information concerning hazardous agents being used as outlined on the biosafety form and ACORP. Information includes agent's host range, ability to infect non-exposed animals, excretion, and selection/use of appropriate personal protective equipment. This information is used by the ACUP Manager to train the animal caretakers. The Centers for Disease Control Biosafety in Microbiological and Biomedical Laboratories handbook is used to determine the biosafety level used for individual hazardous agents. Recommended safety guidelines are followed.

Animals treated with hazardous agents are housed separately from the general population. SOPs are established for hazardous agents being used with research animals. Information for handling animals exposed to hazardous agents is posted on the animal room door and includes agents used, protective precautions, the SDS and the SOP. The hazardous agent is identified on the animal cage card. Untreated animals are fed, watered, and cleaned before the treated animals in order to reduce the risk of contamination. A dedicated bedding disposal station has been obtained for use in the hazardous agent animal housing area. After the study is complete, the animal housing room is decontaminated using appropriate decontamination fluids and measures. All personnel use appropriate PPE equipment as directed from SDS sheets. PPE equipment may include; goggle, gloves, booties, scrubs, gown, and respirator.

**e)** Incidental Animal Contact and Patient Areas

**i)** List and describe facilities that may be used for both animal- and human-based research or patient areas, including the policies and procedures for human patient protection, facility decontamination, animal transport through common corridors or elevators, and other personnel protection procedures.

Not applicable

ii) Describe any *other* circumstances in which animals or caging equipment are transported in common use corridors or elevators (e.g., have the potential to come in contact with individuals not associated with the animal care and use program), and measures taken to mitigate risks associated with such use.

If animals are transported outside treatment rooms to a lab within the VMU they are placed on a cart for transport. This ensures cages are not accidentally dropped during transport. Cages are covered with isolator tops or a "Chux" pad to help contain any contaminants that may escape cages during transport. Doors in the facility are posted BSL-2 and persons entering the VMU are under escort or have previously been trained to work in the VMU. During training it is stressed what precautions and measures are to be taken to ensure containment of hazard potentials. If persons enter the building and do not usually work in the VMU, they are under escort and or have had Biological Hazard training as per VA policy.

## B. Program Oversight

### 1. The Role of the IACUC/OB [*Guide*, pp. 24-40]

**a. IACUC/OB Composition and Function** [*Guide*, pp. 17; 24-25]
Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division) as **Appendix 7**.

**i.** Describe Committee membership appointment procedures.

**Who appoints Committee/who is Institutional Official**

(b)(6)

The IACUC in consultation with the R&D Committee forwards the names of nominees for the IACUC to the IO. The IO officially appoints

members in writing to specific length of appointments. Members are appointed for three years.

The Chairperson is a senior scientist and is appointed in writing by the IO for a term of one year.

**Composition of the Committee**
The BVAMC IACUC consists of 7 voting members:
Members affiliated with the BVAMC:

(b)(6)

Members not affiliated with the BVAMC

(b)(6)

Ex-officio/Non-voting Member

(b)(6)

Members may be re-nominated and serve additional three-year terms. The chair may be re-nominated and serve additional terms. Nominations are submitted to the R& D Committee and appointments made by the IO.

**ii.** Describe frequency of Committee meetings. Note that **Appendix 8** should contain the last two IACUC/OB meeting minutes.

The IACUC meets on the fourth Wednesday of each month when there is business to conduct, or at least quarterly.

**iii.** Describe the orientation, training, and continuing education opportunities for IACUC/OB members. [*Guide*, p. 17]

New IACUC members are welcomed by the Chairperson and the AO/ACOS/R&D. Each new member receives an orientation packet

containing the BVAMC Memorandum 151-17-02, IACUC. This memorandum outlines the purpose, policy, actions, and responsibilities of the IACUC and its members. They also receive a copy of the newest edition of The Guide. New members are enrolled in CITI web-based training and the Occupational Health and Safety Program conducted by the Employee Health Office.

Continuing education for IACUC is conducted periodically as material is available usually during monthly meetings.

When the budget allows, IACUC members are encouraged to attend other continuing education opportunities such as IACUC 101 training.

**b. Protocol Review** [*Guide*, pp. 25-27]
A blank copy of your institution's protocol review form should be provided as **Appendix 9**. Also include forms used for annual renewal, modifications, amendments, etc., as applicable.

**i.** Describe the process for reviewing and approving animal use. Include descriptions of how:

- the IACUC/OB weighs the potential adverse effects of the study against the potential benefits that may result from the use ("harm-benefit analysis"),
- protocols that have the potential to cause pain or distress to animals are reviewed and alternative methodologies reviewed,
- veterinary input is provided, and
- the use of animals and experimental group sizes are justified.

*Note:* Make sure you address each of the items above.

Overall, the process to review and approve animal use is the VA Central Office, Animal Component of Research Protocol (ACORP) version 4; have the animal protocol reviewed and approved by the IACUC; have the R&D committee review and approve the final project with all committees having approved the project.
The ACORP is the document used by the PI to present details of his animal protocol.

The ACORP is first reviewed by the CV and the IACUC chair

(veterinary input provided). Together they discuss the following identified in the ACORP: potential adverse events against the potential benefits that may result; the protocol potential to cause pain and distress and the use of the animal species and experimental group sizes and the extent of experience and or training of the PI and staff to conduct the protocol.

After review by the CV and the IACUC chair, the PI is called and the issues outlined above during the review are discussed between the PI, the CV and the IACUC chair. Discussion usually leads to either justification for the methods based in science from reviewed literature by the PI and the CV and the IACUC chair or the discussion moves toward making modifications to the protocol to ensure the adverse effects do not cause harm and that the benefits outweigh the harm; the pain and distress to the animal is reduced as much as possible, an appropriate endpoint or a different analgesia is used to reduce pain severity and duration; the type of animals used and the number of animals is adequate to use as few animals as possible to get the most credible results possible, a statistician may be called in to help reduce the number of animals and still have valid results, and that training to conduct the protocol has been conducted by qualified individuals and competencies approved by the CV.

The IACUC may request input from outside experts to evaluate portions of the animal study. If specific procedures are unknown elements, the IACUC may request a small group of animals be used to perfect techniques or refine procedures.

After this discussion, and the CV and IACUC chair are satisfied with the PI's responses, the PI makes any changes required and then the full IACUC reviews the protocol and considers the same issues the CV and the IACUC chair did. The IACUC discusses the protocol. The PI is asked to come present an overview of the protocol and to respond to questions. The PI leaves the room, the IACUC conducts further discussion and a motion is made to approve, not approve, or require more information for the protocol to be approved.

Two approval mechanisms may be used by the IACUC: 1) Full Committee Review (FCR): The ACORP is routed to the IACUC for full committee review at a scheduled meeting. If approved by the majority (quorum) of members present at a convened meeting, a memorandum giving IACUC approval is sent to the PI. If substantive modifications/changes are requested in order to secure approval, the IACUC votes to defer and "require modifications/changes in order to secure approval" and the PI is notified in writing. After the PI has met requirements in order to secure approval by the IACUC, the revised ACORP can be sent for FCR or Designated Member Review (DMR). 2) Designated Member Review (DMR): DMR is used for approval of ACORP modifications. The modification is routed to all IACUC members, and all IACUC members are given the opportunity to request FCR of the ACORP modification. If FCR is requested by any IACUC member, approval of the ACORP modification may be granted only after review by the majority (quorum) of members present at the convened meeting. If FCR is not requested by any IACUC member, the IACUC Chair may select two qualified IACUC members to perform the review/approval on behalf of the full IACUC. Results of the DMR are sent in writing to the PI and reported to the full IACUC at the next convened meeting.

All ACORPS are reviewed using one of these two procedures. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g. is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

Prior to the third-year anniversary date of an ACORP, a new ACORP must be submitted for IACUC approval. The IACUC determines that all activities involving animals meet the requirements of The Guide, unless specific departures are scientifically justified in writing by the PI.

**ii.** Describe the process for reviewing and approving amendments, modifications, and revised protocols. If applicable, include a

description/definition of "major" vs. "minor" amendments.
*Note:* If preferred, this information may be provided in a Table or additional Appendix.

A "Request to Modify Animal Use" form is used for any modifications requested such as changes in study personnel, study procedures, or manipulations. Approval mechanisms used by the IACUC for revised protocols or changes to the ACORP are either the FCR or DMR.

Major modifications that would require FCR would include changes in study objectives, procedures, changing surgical procedures from nonsurvival to survival surgery, minor to major surgery, single surgical procedure to multiple surgical procedures, changing animal model or type, changes in the degree of invasiveness of procedures, increases in morbidity or pain, changes in anesthetic or analgesics, or methods of euthanasia and changes in PI.

If the ACORP contains multiple complicated modifications and is difficult to follow, the IACUC may request the ACORP be re-written and all modifications incorporated prior to the required third year renewal of the ACORP.

If it is unclear whether a modification is insignificant, the IACUC Chair should be involved in determining as to whether or not the modification is significant. The Chair may refer to OLAW guidance as to what constitutes a significant change. A modification that proposes a new potentially painful or distressful procedure should be developed in consultation with the CV and alternatives should be considered.

Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, personnel changes etc. may be confirmed by IACUC administrative/support personnel.

**c. Special Considerations for IACUC/OB Review** [*Guide*, pp. 5; 27-33]

**i. Experimental and Humane Endpoints** [*Guide*, pp. 27-28]

1) Describe the IACUC/OB's review of "humane endpoints," i.e., alternatives to experimental endpoints to prevent or in response to unrelieved animal pain and distress.

In all projects involving animals, the PI is required to seek alternative model systems for the work proposed. Seeking such alternatives may involve consultation with the CV or established investigators that utilize animals for similar work, as well as a broad-based literature search. As part of the ACORP, each PI must provide, in writing, the details of any such consultations as well as the complete database search criteria used to determine whether such alternative models exist, including the database name, the key search terms utilized and the period covered by the search. Should a possible alternative model be identified, the PI must, in his/her best scientific judgment, determine whether the alternative adequately meets the scientific goals of the study. If the alternative system is deemed scientifically unsuitable, the PI must provide a written justification, as part of the ACORP, as to how/why this decision was reached.

In the ACORP, the PI must provide assessment criteria involved in the endpoint, the monitoring plan including the frequency of animal observation, and personnel responsible for monitoring.

The IACUC may ask that the PI use a small group of animals to identify and define a humane endpoint if alternative endpoint information is not available. A humane endpoint needs to be determined between the PI, the CV, and the IACUC.
Similarly, for work involving animals, all PIs are encouraged, whenever scientifically feasible, to incorporate those endpoints that are generally accepted as humane as outlined in The Guide. Use of endpoints other than those generally accepted as humane must be scientifically justified in writing and must include a description of why an alternative, more humane endpoint is not suitable.

2) For studies in which humane alternative endpoints are not available, describe the IACUC/OB's consideration of animal monitoring and other means used to minimize pain and distress (e.g., pilot studies, special

monitoring, other alternatives).

If there is a study for which a humane alternative endpoint is not available, the IACUC may ask that the PI use a small group of animals to identify and define a humane endpoint. A humane endpoint needs to be determined between the PI, the CV, and the IACUC.

Similarly, for work involving animals, all PIs are encouraged, whenever scientifically feasible, to incorporate those endpoints that are generally accepted as humane as outlined in The Guide. Use of endpoints other than those generally accepted as humane must be scientifically justified in writing and must include a description of why an alternative, more humane endpoint is not suitable.

**3)** Identify personnel responsible for monitoring animals for potential pain and distress and describe any mechanisms in place to ensure that the personnel have received appropriate species- and study-specific training.

For each study, animals are monitored by the PI and study personnel throughout the day and evening if necessary. The VMU staff also monitor the animals during their daily rounds or when changing cages, food and water. All of these monitors have received specific training in CITI for the specific animal species they are working with. The training compliance is monitored by the VMU Manager and the Research Admin office. Assurance that these individuals are sufficiently trained is documented from the online trainings, the in person trainings and competency documents from the CV and/or the PI.

**ii. Unexpected Outcomes that Affect Animal Well-being** [*Guide*, pp. 28-29]
Describe how unexpected outcomes of experimental procedures (e.g., unexpected morbidity or mortality, unanticipated phenotypes in genetically-modified animals) are identified, interpreted, and reported to the IACUC/OB.

Unexpected outcomes, morbidity or mortality are identified, interpreted and reported to the IACUC.

Unexpected outcomes, morbidity and mortality are identified by those

individuals monitoring the animals after treatment: the PI, study staff and VMU staff. The signs of unexpected outcomes and morbidity are provided in the ACORP. Monitors are trained to recognize signs and symptoms in animals displaying unusual behavior or illness.
Unexpected mortality is identified as death to the animal earlier than expected or described in the ACORP. These things are recorded on the cage cards in the animal rooms.
Interpretation of the outcomes, morbidity and mortality may be discussed and interpreted collectively by the research group, the CV and the VMU staff.

These outcomes may be reported and discussed with the IACUC. The BVAMC program adheres to the BVAMC Medical Center Memorandum 151-17-13, *Reporting Requirements for Research Noncompliance Events Including Complaints and Allegations of Research Noncompliance*. In all cases, reports of unexpected outcomes including unexpected death are reported to the IACUC within 5 business days of becoming aware of the apparent unexpected outcome or unexpected death. If there are incidents related to animal welfare and safety, these should be reported in writing to the IACUC within 5 business days of becoming aware of the incident.

**iii. Physical Restraint** [*Guide*, pp. 29-30]
*Note:* This section is to include only those protocols that require prolonged restraint. Brief restraint for the purpose of performing routine clinical or experimental procedures need not be described.

**1)** Briefly describe the policies for the use of physical restraint procedures or devices. Include, if applicable, the IACUC/OB definition of "prolonged."

Currently there are no approved protocols for prolonged restraint.

Restraint devices should be suitable in size, design, and operation to minimize discomfort, pain, distress or potential for injury to both animals and study personnel. Restraint devices used must be justified in the study ACORP. Devices are not to be used as a convenience in handling or managing animals and are not to be used as a method of housing animals.

2) Describe animal restraint devices that are used or have been used within the last three years. For each device, briefly describe
   - the duration of confinement
   - acclimation procedures
   - monitoring procedures
   - criteria for removing animals that do not adapt or acclimate, and
   - provision of veterinary care for animals with adverse clinical consequences.

   *Note:* If preferred, this information may be provided in a Table or additional Appendix.

Currently and within the past three years there have been no approved protocols using prolonged restraint.

**iv. Multiple Survival Surgical Procedures** [*Guide*, p. 30]
*Note:* One survival surgical procedure followed by a non-survival procedure is not included in this category.

1) Describe the IACUC/OB's expectations regarding multiple survival surgery (major or minor) on a single animal.

The BVAMC does not practice or encourage multiple survival surgeries. being done at the BVAMC.

The BVAMC, VMU SOP June 2017, Appendix F, states Regardless of classification, multiple surgical procedures on a single animal should be evaluated to determine their impact on the animal's well-being. Multiple major surgical procedures on a single animal are acceptable only if they are (1) included in and are essential components of a single research project or protocol, (2) scientifically justified by the investigator, or (3) necessary for clinical reasons. Major surgery penetrates and exposes a body cavity or produces substantial impairment of physical or physiologic function. Some procedures characterized as minor may induce

substantial post-procedural pain or impairment and should be scientifically justified if performed more than once in a single animal.

Justifications for allowing animals not regulated by the USDA (mice and rats) to undergo multiple survival procedures that meet the above criteria should conform to those required for regulated species.

USDA regulated species that are to undergo multiple major survival surgical procedures in separate unrelated research protocols must first have the Institutional Official submit a request and receive approval from the USDA/APHIS. (USDA 1985, 1997a).

**2)** Summarize the types of protocols currently approved that involve multiple major survival surgical procedures

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

Not applicable. Multiple survival surgeries are not being done at the BVAMC.

**v. Food and Fluid Regulation** [*Guide*, pp. 30-31]. *Note:* This does not include pre-surgical fast.

Summarize the types of protocols that require food and/or fluid regulation or restriction, including:

- justification
- species involved
- length and type of food/fluid regulation
- animal health monitoring procedures and frequency (e.g., body weight, blood urea nitrogen, urine/fecal output, food/fluid consumption)
- methods of ensuring adequate nutrition and hydration during the regulated period

*Note:* If preferred, this information may be provided in a Table or additional Appendix.

Not applicable.

There are currently no approved ACORPs restricting or controlling access to food or fluids.

**vi. Use of Non-Pharmaceutical-Grade Drugs and Other Substances** [*Guide*, p. 31]

Describe the IACUC/OB's expectations regarding the justification for using non-pharmaceutical-grade drugs or other substances, if applicable.

Administration of non-pharmaceutical grade drugs or other such substances to experimental animals is strongly discouraged. Requests for administration of such substances must be scientifically and ethically justified in writing by the PI and presented for IACUC discussion and approval. The rationale that such substances are less expensive is NOT considered to be adequate justification for such a practice. Exceptions would be if a veterinary or human pharmaceutical grade product is not available or when the substances are unable to meet the scientific goals of the project.

**vii. Field Investigations** [*Guide*, p. 32]

Describe any additional considerations used by the IACUC/OB when reviewing field investigations of animals (non-domesticated vertebrate species), if applicable.

Not applicable.
We have no field investigations of animals.

**viii. Animal Reuse** [*Guide*, p. 5]

**1)** Describe institutional policies regarding, and oversight of, animal reuse (i.e., on multiple teaching or research protocols).

Study animals are not to be reused. Our institution and resources do not permit such protocols to be conducted.

**2)** Briefly describe the types of activities currently approved that involve the reuse of individual animals.
*Note*: A list of specific protocols involving reuse of animals should be available during the site visit.

Study animals are not to be reused. Our institution and resources do not permit such protocols to be conducted.

3) Describe other instances where the final disposition of animals following study does not involve euthanasia, including adoption, re-homing, rehabilitation, etc.
*Note*: A list of specific protocols involving reuse of animals should be available during the site visit.

Study animals are not to be reused. Our institution and resources do not permit such protocols to be conducted.

2. **Post-Approval Monitoring** [*Guide*, pp. 33-34]

a. Describe mechanisms for IACUC/OB review of ongoing studies and periodic proposal/protocol reviews (e.g., annual, biennial, triennial, or other frequency).

The IACUC can assign a monitor, usually the CV, the ACUP Manager, or the chair, to review ongoing study records and assure PIs and study personnel are following approved protocols. The monitors report back to the IACUC. The IACUC can also work with the RCO who reviews study records to assure compliance.

Mechanisms for periodic reviews include annual reviews, review during request for modifications and the three-year renewal when the whole protocol must be reviewed regardless of any changes. All reviews are conducted by the IACUC.

c. Describe the process and frequency with which the IACUC/OB conducts facility and laboratory inspections.
- Describe the rationale or criteria used for exempting or varying the frequency of reviewing satellite holding facilities and/or animal use areas.
- If contract facilities or contractor-provided personnel are used, describe procedures used by the IACUC/OB to review such programs and facilities.

*Note:* A copy of the last report of these reviews should be included as **Appendix 10**.

The IACUC uses the VA semiannual evaluation of the Institutional

Animal Care and Use Program and Facilities checklists as the primary inspection of the animal program and the VMU. The semi-annual reviews by the hospital GEMS and Environment of Care Committees (EOCC) also inspect the labs and the VMU for compliance with BVAMC policies and protocols for personal safety and safety using hazardous agents. The VA semiannual evaluation checklist contains three major areas: Review of the Program; Facilities; and Deficiencies/Post Review. Each major area consists of four inspection areas with each inspection area containing a subset of items and items listing various criteria for compliance. The four inspection areas are: Implementation of Institutional Policies; Physical Plant; Animal Environment, Housing and Management; and Veterinary Medical Care.

The following IACUC members are required to conduct the VA semiannual evaluation: IACUC Chair, CV, and at least one other IACUC member. Others may join if they can. The review team walks through the VMU with the checklists and read each checklist item out loud, discusses any issues around the checklist item then votes as to whether compliance for the item has been not applicable, acceptable, or if deficiencies exist and if that is the case, are the deficiencies minor or significant. Another area of the checklist includes listing animal facility work orders. The list contains each work order date of origin and number of days to completion.

The completed semiannual evaluation is then presented to the IO by the review team and the ACOS/R&D and AO/ACOS/R&D. At this time issues and challenges regarding the program and animal facility are brought to the MCD's attention. Suggested solutions are presented for consideration and discussion.

We have no satellite holding facilities or contract facilities. The last semiannual evaluation is attached as an appendix.

**d.** If applicable, summarize deficiencies noted during external regulatory inspections within the past three years (e.g., funding agencies, government, or other regulatory agencies) and describe institutional responses to those deficiencies. *Note:* Copies of all such inspection reports (if available) should be available for review by the site visitors.

Institutional responses to deficiencies noted on regulatory inspection reports are dealt with as follows: Reports of deficiencies are received by the IO and the ACOS/R&D with copies to the AO/ACOS/R&D. The AO/ACOS/R&D works with appropriate staff or research personnel to develop a corrective action plan and timeline addressing the deficiencies in consultation with the RCO and regulatory body as needed. The corrective action plan and timeline is reviewed and approved by the ACOS/R&D and the IO and forwarded to the regulatory agency for review and approval. The AO/ACOS/R&D then ensures the action plan is implemented, monitored, and reported through the ACOS/R&D and the IO to the regulatory agency based upon the agreed upon timeline. Conference calls may occur between the R&D administrative staff and the regulatory agency throughout the process to respond to questions or issues that may arise as the corrective action plan is being implemented.

**e.** Describe any other monitoring mechanisms or procedures used to facilitate ongoing protocol assessment and compliance, if applicable.

The RCO does regular compliance checks to assess the following: training compliance, adherence to ACORPs, PI credentialing, required research study paperwork such as required documentation of veterinary competencies, use of chemical and hazardous materials documentation, etc.

**3. Investigating and Reporting Animal Welfare Concerns** [*Guide*, pp. 23-24]
Describe institutional methods for reporting and investigating animal welfare concerns.

Responsibility for review and investigation of animal welfare concerns rests with the IO and the IACUC. Any individual with concerns about the treatment, husbandry, or well-being of any research animal in the VMU is encouraged to express these concerns, and to be satisfied that the issues of concern are resolved. All concerns are taken seriously and will be addressed by the IACUC and will be held in strict confidence.

Contact either of the following people listed:

(b)(6)

(b)(6)

If the above does not satisfactorily resolve valid concerns, the individual should contact the ACOS/R&D (b)(6) or the IO (b)(6) (b)(6)

Information regarding reporting of animal welfare concerns is posted at entrances and in the main hallway of the VMU.

BVAMC Memorandum 151-17-13 entitled Reporting Requirements for Research Noncompliance Events Including Complaints and Allegations of Research Noncompliance. Attachment A of that memorandum provide detailed flow charts and tables on the reporting mechanisms, reporting process, appropriate oversight agencies and timeframes related to animal research noncompliance. Animal welfare and other animal research related concerns are reported in writing to the IACUC by the PI, RCO or the VA research community, as soon as possible, but no later than five business days after becoming aware of the event. Within 5 days of the determination, the IACUC Chairperson must report the research events to the IO and the ACOS/R&D. The IO must then report the incident to ORO within 5 days of receiving the IACUC review. The IO is responsible for ensuring compliance with reporting requirements of research events related to animal research.

4. **Disaster Planning and Emergency Preparedness** [*Guide* p. 35]
Briefly describe the plan for responding to a disaster potentially impacting the animal care and use program:
   - Identify those institutional components and personnel which would participate in the response.
   - Briefly describe provisions for addressing animal needs and minimizing impact to animal welfare.

*Note:* A copy of disaster plan(s) impacting the animal care and use program must be available for review by the site visitors.

- In the case of a disaster facility personnel have been trained to initiate a phone tree and contact the AO. The AO would then notify the VMU

Manager and the Manager would contact the PI's with any animals in the facility. If communication is compromised and cell phones do not work a white board is to be utilized at the entrance to the building. This board will note when animals were cared for and what was done.

- Disaster planning for animal needs may include covering animal racks with blankets in case of heat loss and possibly relocating animals to an interior room to minimize extreme temperature fluctuation. Research has purchased four oil filled heaters that can be used in individual animal housing rooms to maintain heat in the event of a system failure. In the event of electrical power is not operating, fans may also be obtained from FMS to use in individual animal rooms in the event of elevated temperature extremes.

## II. Animal Environment, Housing and Management

*Note:* Complete each section including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

### A. Animal Environment

*Note*: Facility-specific details regarding mechanical system construction and operation is requested in Section IV.B.5. and **Appendix 11**; current (measured ***within the last 12 months***), detailed (by room) performance data must also be provided as indicated in **Appendix 11.**

#### 1. Temperature and Humidity [*Guide*, pp. 43-45]

**a.** Describe the methods and frequencies of assessing, monitoring, and documenting that animal room or housing area temperature and humidity is appropriate for each species.
*Note:* If preferred, this information may be provided in a Table or additional Appendix.

The VMU utilizes hot-water heat geothermal wells located on the premises. The building is cooled by a chilled-water cooling system using 100% fresh air. Individual animal room temperatures are controlled by in-line duct thermostats located in the mechanical space above each room. Air conditioning is alarmed with high-temperature sensors placed in the main exhaust duct. The sensor activates an audible alarm at 80°F that sounds in Facilities Management Service (FMS) where the web-based

Direct Digital Control (DDC) System monitors the room temperatures. This system is monitored 24/7 by qualified FMS personnel. All animal rooms have controlled humidity, ranging between 30% and 70%. Each animal room is equipped with a thermometer and humidity sensor that is monitored and recorded daily.

**b.** List, by species, set-points and daily fluctuations considered acceptable for animal holding room temperature and relative humidity.
*Note:* If preferred, this information may be provided in a Table or additional Appendix. [*Guide*, pp. 44 and 139-140]

Mice or Hamsters are set at 68-79 °F, with a daily fluctuation acceptable to 3 °F above or below. In excess and environmental alarms will trigger. Relative humidity is maintained at a 30-70% humidity range.

**c.** Temperature set-points in animal housing rooms and/or environmental conditions are often outside of the species-specific thermoneutral zone. Describe the process for enabling behavioral thermoregulation (e.g., nesting material, shelter, etc.) or other means used to ensure that animals can control their thermoregulatory environment. Include a description of IACUC/OB approved exceptions, if applicable. [*Guide*, p. 43]

Temperature ranges for species used in the VMU are within the recommended ranges as stated in The Guide. Mice are provided with nesting materials and disposable or poly carbonate mouse houses to allow them to thermo-regulate by controlling their microclimate. Exceptions to recommended temperature ranges must be justified on the ACORP and be approved by the IACUC.

**2. Ventilation and Air Quality** [*Guide*, pp. 45-47]

**a.** Describe the methods and frequencies of assessing, monitoring, and documenting the animal room ventilation rates and pressure gradients (with respect to adjacent areas).
*Note:* If preferred, this information may be provided in a Table or additional Appendix.

The animal room ventilation rates are assessed every three years or more often as needed. A calibrated ventilation hood measures supply and exhaust air at each outlet. Air exchanges are calculated based on supply

and exhaust air flow rates. Records are documented and maintained by the BVAMC Engineering Service. The system consists of dual compressors.

Description of Filtration/Treatment of Recycled Air
Feed room 137 has recirculated air. It is recirculated through a coarse filter.

**b.** Describe ventilation aspects of any special primary enclosures using forced ventilation.

Not applicable

**c.** If any supply air used in a room or primary enclosure is recycled, describe the percent and source of the air and how gaseous and particulate contaminants are removed.

Food and bedding storage room 137 uses 100% recirculated air. The room pressure is neutral and air is returned through a course filter to this room only.

**3. Life Support Systems for Aquatic Species** [*Guide*, pp. 84-87]

**a.** Provide a general description of institutional requirements for enclosures using water as the primary environmental medium for a species (e.g., aquatics).

Not applicable

**b.** Provide a general description of overall system(s) design, housing densities, and water treatment, maintenance, and quality assurance that are used to ensure species appropriateness.
*Note*: Facility-specific tank design and parameter monitoring frequencies should be summarized in **Appendix 12** (Aquatic Systems Summary).

Not applicable

**4. Noise and Vibration** [*Guide*, pp. 49-50]
Describe facility design features and other methods used to control, reduce, or prevent excessive noise and vibration in the animal facility.

There are six animal housing rooms open into an exclusive corridor, separated

from the main corridor by a single door. One animal room opens into another animal room. A cluster of four rooms opens into an exclusive corridor, separated from the main corridor by a noise lock. Animal caging racks are equipped with rubber casters and carts are equipped with rubber casters and bumpers.
The animal facility exterior walls are eight inches thick concrete masonry block filled with sand. The dirty-cage wash room, (b)(6) has six-inch-thick concrete masonry block walls. All doors are made of metal with automatic closures except for solid wood doors in administration area.

The clean cage area and one storage room are equipped with heavy duty plastic fork lift doors with automatic closures.

No background noise system is used.

**B. Animal Housing** (all terrestrial, flighted, and aquatic species)

**1. Primary Enclosures**
*Note:* A description of primary enclosures used (e.g., cages (conventional, individually-ventilated cage systems (IVCS), etc.), pens, stalls, pastures, aviaries, tanks) should be included in **Appendix 13**.

**a.** Describe considerations, performance criteria and guiding documents (e.g. *Guide*, *Ag Guide*, ETS 123 and/or other applicable standards) used by the IACUC/OB to verify adequacy of space provided for all research animals, including traditional laboratory animal species, agricultural animals, aquatic species, and wildlife when reviewing biomedical, field and agricultural research studies.

**Indoor Animal Housing**

Rodent rooms' temperatures are maintained between 70°F and 72°F. Humidity ranges between 30% and 70%. Mice are housed in pairs or groups in 11" L x 7" W x 5" D or 18" L x 9.5" W x 6" D clear solid bottom polycarbonate rigid cages with laboratory grade hardwood shavings bedding. Cages are either placed in a stainless-steel hanging rack or placed on stainless steel racks and stainless-steel lid wire is used for cage top. Mice are provided ad lib access to water using glass or polycarbonate water bottles with stainless steel sipper tubes. Ad lib access

to quality rodent diet is provided in stainless steel hanging feeder attached inside cage or placed in food portion of stainless steel cage lid. Mouse room temperature is maintained between 70°F and 72°F. Humidity ranges between 30% and 70%. Nude mice are housed in pairs or groups as above in 11" L x 7" W x 5" D or 18" L x 9.5" W x 6" D cages with filtered micro-isolation lids. Cage units including cage, stainless steel wire lid, water bottle, sipper tube, and isolator lid are autoclaved prior to use. Laboratory grade hardwood bedding is autoclaved. Food and water is provided as above, except food and water has been autoclaved. Water is acidified to 2.5-2.8 by the addition of hydrochloric acid. Nude mouse room temperature is maintained at 74°F with humidity ranging between 30% to 70%. Mouse room access is restricted by a locked door.

Group housing and animal density is determined using The Guide as a reference and taking into consideration species and strain characteristics such as age, size, sex, behavior, health status, and overall design of protocol.

**References and Considerations Used to Determine Cage or Pen Size or Housing Densities**

Cage and housing densities are determined by The Guide guidelines, as well as consultation with the CV, PI, and the IACUC. Floor space, housing densities, and social housing are determined according to a) species, strain, breed, age, size, sex, behavior and health status, b) the overall design and construction of housing, and c) the design of the animal protocol which may require special consideration.

**b.** Describe space exceptions to the guiding documents (*Guide*, *Ag Guide*, ETS 123, and/or applicable standards), indicating the references, considerations and performance criteria used (e.g., by the IACUC/OB) to verify adequacy of space provided for all animal species covered by the program. [*Guide*, pp. 55-63]

Currently, there are no exceptions.
If there is a need for an exception in the future, housing size and densities would be reviewed and modified as necessary to accommodate individual needs by consultation with VMU personnel, the PI, the CV, and approval of the IACUC.

2. **Environmental Enrichment, Social, and Behavioral Management** [*Guide*, pp. 52-55; 63-65: *Ag Guide*, Chapter 4]

   a. **Environmental Enrichment**

      i. Describe the structural elements of the environment of primary enclosures that may enhance the well-being of animals housed (e.g., resting boards, privacy areas, shelves/perches, swings, hammocks).

      Rodent cages are made of clear polycarbonate with a solid bottom to provide sufficient light, observation with minimal disturbance and visual exposure to animals of the same species that are housed in the surrounding area.

      ii. Describe nonstructural provisions to encourage animals to exhibit species typical activity patterns (e.g., exercise, gnawing, access to pens, opportunity for exploration, control over environment, foraging, denning, burrowing, nesting materials, toys/manipulanda, browsing, grazing, rooting, climbing).

      Hardwood bedding is used in solid bottomed cages to allow nesting behavior. Conventionally housed mice are provided with disposable mouse houses and nesting material. Immunocompromised mice are provided with autoclaved polycarbonate mouse houses. Sanitized pieces of PVC pipe may also be used. Animals are also provided with an opportunity with daily interaction with VMU personnel. Polycarbonate exercise wheels are provided to all animals as an option if protocols allow.

   b. **Social Environment** [*Guide*, p. 64]

      i. Describe institutional expectations or strategies for <u>social housing</u> of animals.

      Non-social housing of social animals will be discussed between the PI and the CV during the initial review of the ACORP. Justification to not house social animals socially must be provided and based on experimental design or veterinary concerns.

      ii. Describe exceptions to these expectations (e.g., veterinary care, social incompatibility) and other typical justification approved by the IACUC/OB for

housing animals individually.

Exceptions to non-social housing may include an animal's aggressive behavior, injury or study aims. These exceptions must first be approved by the IACUC and be conducted for the shortest period of time possible. When possible, animals will be placed within visual, auditory, and olfactory proximity of animals of the same species. Efforts will be made to provide additional environmental enrichments and opportunities to interact with VMU personnel.

**iii.** Describe steps taken with isolated or individually housed animals to compensate for the absence of other animals (interaction with humans, environmental enrichment, etc.).

Mice that must be housed individually are placed on the same rack shelf as other mice to provide auditory, visual and olfactory contact. They are also provided the same environmental enrichments. The PI may request exceptions as noted in the Research Environmental Enrichment Policy. Efforts will be made to provide additional environmental enrichments and opportunities to interact with VMU personnel.

**c. Enrichment, Social and Behavioral Management Program Review** [*Guide*, pp. 58, 69]
Describe how enrichment programs and exceptions to social housing of social species are regularly reviewed to ensure that they are beneficial to animal well-being and consistent with the goals of animal use.

The VMU SOP includes a description of the Research Environmental Enrichment Policy that addresses social grouping, enrichment devices and special considerations. The SOP and the enrichment policy is reviewed annually by IACUC. The PI may request exemptions as noted in the Research Environmental Enrichment Policy.

**d. Procedural Habituation and Training of Animals** [*Guide*, pp. 64-65]
Describe how animals are habituated to routine husbandry or experimental procedures, when possible, to assist animals to better cope with their environment by reducing stress associated with novel procedures or people.

Animals requiring the use of restrainers during experiments will be acclimated to equipment and procedures will be described in the ACORP. Descriptions should include the number of times the animal will be acclimated and number of times the animal will be in the restrainer, etc. VMU personnel will move young litters of pups by gently scooping the entire nest in a large stainless-steel spoon and placing the nest in a clean cage to minimize disturbance of the nest and stress of female mouse.

**e. Sheltered or Outdoor Housing** [*Guide*, pp. 54-55]

**i.** Describe the environment (e.g., barn, corral, pasture, field enclosure, flight cage, pond, or island).

BVAMC has no animals housed outside.

**ii.** Describe methods used to protect animals from weather extremes, predators, and escape (windbreaks, shelters, shaded areas, areas with forced ventilation, heat radiating structures, access to conditioned spaces, etc.).

Not applicable

**iii.** Describe protective or escape mechanisms for submissive animals, how access to food and water is assured, provisions for enrichment, and efforts to group compatible animals.

Not applicable

**f. Naturalistic Environments** [*Guide*, p. 55]

**i.** Describe types of naturalistic environments (forests, islands) and how animals are monitored for animal well-being (e.g., overall health, protection from predation).

Not applicable

**ii.** Describe how food, water, and shelter are provided.

Not applicable

**iii.** Describe how animals are captured.

Not applicable

## C. Animal Facility Management

### 1. Husbandry

#### a. Food [*Guide*, pp. 65-67]

**i.** List type and source of food stuffs.

**Type and Source**
Commercially prepared pelleted diets are obtained from certified vendors. Taconic provides autoclaved, pelleted rodent diet. Harlan Teklad provides pelleted rodent diet.

**ii.** Describe feed storage facilities, noting temperature, relative humidity, and vermin control measures, and container (e.g., bag) handling practices, for each of the following:

- vendors (if more than one source, describe each)
- centralized or bulk food storage facilities if applicable
- animal facility or vivarium feed storage rooms
- storage containers within animal holding rooms

Commercially prepared pelleted diets are obtained from certified vendors. Taconic provides autoclaved, pelleted rodent diet. Harlan Teklad provides pelleted rodent diet.
Taconic's autoclaved rodent diet is stored in a fridge/freezer at 36°F in (b)(6) The food is code dated and rotated. Food storage is in a climate-controlled metal building with a concrete floor. Traps are used for vermin control.
Harlan Teklad is certified by the International Standardization Organization for manufacturing animal diets. The storage facility is a metal building with cement floors. Temperatures are kept at 70°F or less with humidity at 55% or less. Food is code dated, properly rotated and stored on single use pressed wood pallets on a shelf racking system. The building has an 18-inch perimeter around the inside in which glue traps are used for vermin control.

Pelleted diets are kept in (b)(6) of the animal facility on wire shelving rack in a refrigerator/freezer or enclosed plastic storage containers. Refrigerator unit maintains the feed at an approximate temperature of 36°F. An external room door has a solid steel barrier extending 24 inches from the floor to prevent vermin entry. Premises are inspected weekly for evidence of vermin. If there is evidence of vermin, FMS (responsible for pest control) is contacted.

Individual animal rooms have durable plastic barrels or buckets with tight fitting lids that contain pelleted diets. Each food container is labeled with contents, mill date, and the date feed is opened for use.

**iii.** Describe special food preparation areas, such as feedmills and locations where special diets are formulated, if applicable. Include in the description sanitation and personnel safety practices (noting that respiratory protection is described in Section 2.I.A.2.b. ii. Standard Working Conditions and Baseline Precautions above).

Not applicable

**iv.** Describe how food is provided to various species (*ad libitum*, limited amounts, types of feeders).

Mice are fed pelleted diet ad lib in the food compartment of the stainless-steel cage lid.

**v.** Describe special food quality control procedures including procedures for rotating stock, monitoring milling dates, nutritional quality, bio load, chemical contaminants, etc.

Food is rotated each time a new shipment comes in, and is used within 180 days of milling. Milling dates of incoming shipments are recorded and food usage is logged. All food is commercially prepared and guaranteed by vendors.

**b. Drinking Water** [*Guide*, pp. 67-68]

**i.** Describe the water source, treatment or purification process, and how it is provided to the animals (e.g., bowls, bottles with sipper tubes, automatic

watering, troughs, ponds, streams).

United Water System provides the water for the VMU. All rodents use water bottles and sipper tubes.

**ii.** Describe methods of quality control, including monitoring for contaminants.

United Water complies with all contaminant testing required by the Federal Safe Drinking Water Regulations.

**iii.** If automatic water delivery systems are used, describe how they are maintained and sanitized.

Not applicable

**c. Bedding and Nesting Materials** [*Guide*, pp. 68-69]

**i.** Describe type(s) and how used for various species.

Heat-treated hardwood laboratory bedding is used as contact bedding for rodents obtained from Animal Specialties. Hardwood bedding is selected to reduce aromatic hydrocarbons that have a potential to interfere with study design. It also allows for rodent nesting behavior and provides moisture absorbency. Nesting material for rodents are provided as 2.25" x 2.25" Isoblox short white compressed cotton material obtained through Harlan Laboratories. This is an FDA-approved material for use in humane medical products and food production. Isoblox are hypoallergenic.

**ii.** Describe bulk bedding storage facilities, if applicable, including vermin control measures.

Hardwood bedding is shipped individually wrapped in 33-pound bags and stored on plastic pallets in (b)(6) The storage area is checked weekly for evidence of vermin. Weekly amounts of bedding are stored in an enclosed plastic storage container in (b)(6) for daily access. If there is evidence of vermin, FMS (responsible for pest control) is contacted. External door has a solid steel barrier extending 24 inches from floor to prevent vermin entry.

iii. Describe quality control procedures, including monitoring for contaminants.

Bedding is obtained from a reputable vendor and checked visually upon arrival and again when opened for use. Bedding used for immunocompromised rodents will be autoclaved in small batches at 250 °F for 30 minutes before use. Bedding is rotated upon arrival of each shipment. Bedding is shipped in individually wrapped 33-pound bags and placed on heavy paper wrapping on pallets and shrink-wrapped. Shrink-wrap is not removed until arrival at the VMU.

**d. Miscellaneous Animal Care and Use Equipment**

i. Describe motorized vehicles and other equipment (e.g., trailers) used for transporting animals, noting the type and how the cargo compartment is environmentally controlled, if applicable.

Not applicable

ii. Describe other animal care related equipment used in the animal care program (specialized equipment for exercise or enrichment, high pressure sprayers, vacuum cleaners, tractors, trailers, spreaders, etc.).

Other animal care equipment used in the animal care program includes two high-pressure sprayers, three hepa filtered wet/dry vacuums and one autoclave. Two down draft bedding disposal stations are used when disposing of soiled animal bedding and waste.

**e. Sanitation** [*Guide*, pp. 69-73]

**i. Bedding/Substrate Change**

**1)** Describe frequency of contact and non-contact bedding change for each species and enclosure type (solid-bottom or suspended) or pen.

Solid bottom cages for mice are changed and sanitized twice weekly at a minimum.

**2)** Describe any IACUC/OB approved exceptions to frequencies recommended in the *Guide* or applicable regulations and the criteria used

to justify those exceptions.

There are no exceptions.

3) Note the location where soiled bedding is removed from the cages/enclosures and where clean bedding is placed into the cages/enclosures.

Nonhazardous soiled bedding is removed from cages utilizing a down draft bedding disposal station in the dirty cage washing room (b)(6) Clean bedding is placed in cages and pans in the clean cage drying and storage room (b)(6)
Bedding from animals treated with hazardous or infectious agents is handled as described in the study SOP. Soiled bedding is removed from cages utilizing a down draft bedding disposal station in the centralized corridor of the four rooms used with hazardous agents. This corridor is separated from the main facility corridor by two doors.

**ii. Cleaning and Disinfection of the Micro- and Macro-Environments**
*Note:* A description of the washing/sanitizing frequency, methods, and equipment used should be included in **Appendix 14** (Cleaning and Disinfection of the Micro- and Macro-Environment) and **Appendix 15** (Facilities and Equipment for Sanitizing Materials).

1) Describe any IACUC/OB approved exceptions to the *Guide* (or applicable regulations) recommended sanitation intervals.

Not applicable – there are no exceptions.

2) Assessing the Effectiveness of Sanitation and Mechanical Washer Function

a) Describe how the effectiveness of sanitation procedures is monitored (e.g., water temperature monitoring, microbiological monitoring, visual inspections).

The cage washer water temperature is monitored by washer controls and by using a temperature indicator for each cage wash load containing animal microenvironments. The cage wash cycle

includes one two-minute prewash of 180°F, one five-minute wash of greater than 150°F and two three-minute rinse cycles with the final rinse greater than 180°F. Racks, housing units, and watering and feeding devices are visually inspected before animals are housed. Quality assurance cage washer printer tapes are kept to document and assure proper washing and minimum temperatures are achieved. Monthly microbiological monitoring is performed on cleaning and caging equipment.

**b)** Describe preventive maintenance programs for mechanical washers.

We have an annual preventive maintenance contract with Steris, the cage washer manufacturer. This agreement has an annual renewal option for four years then it must go out on bid. The Steris service representative comes to the VMU quarterly to inspect and calibrate the cage washer, conducts all labor and provides all parts to perform preventive maintenance in accordance with the manufacturer's maintenance checklist. A report and invoice is then sent to the Research Office. The Research Office checks with the ACUP Manager to see if the service was satisfactory and if it is the invoice is paid. If unscheduled repair visits or emergency service is needed, the ACUP Manager directly contacts the service rep by phone who responds via phone within 4 hours and is usually on station for repairs within 48 hours.

**f. Conventional Waste Disposal** [*Guide*, pp. 73-74]
Describe the handling, storage, method and frequency of disposal, and final disposal location for each of the following:

**i.** Soiled bedding and refuse.

Bedding NOT exposed to hazardous or infectious agents
VMU personnel wearing gloves and particulate filter respirators use a down draft bedding disposal station to place bedding from indoor animals (not exposed to hazardous or infectious agents) in double black bags and place in locked carts to be picked up by FMS and taken to an outside contractor two times per week.

Sani Pak equipment consists of a 45-minute cycle of greater than 200°F for 34 minutes and 280°F for 15 minutes, pressure of 38 psi for five minutes and greater than 36.9 psi for seven minutes. The contents are removed by an outside contractor and disposed of in the landfill.

Bedding EXPOSED to hazardous or infectious agents
VMU personnel wearing gloves and particulate filter respirators use a down draft bedding disposal station to place bedding from indoor animals (exposed to hazardous or infectious agents) in double red bags and place in locked red biohazard carts labeled Biohazardous and picked up by FMS two times per week. It is picked up by an outside contractor who autoclaves it and disposes of contents in the landfill.

Soiled bedding and refuse containing chemotherapeutic agents is placed in a yellow bag, then in a grey bag, and placed in the locked red biohazard carts, picked up by FMS and is incinerated by an outside contractor.

**ii.** Animal carcasses.

Rodent carcasses are double-bagged in blue bags for non-hazardous and double red bags for hazardous agents, placed in a dedicated -20°C freezer located in (b)(6) and emptied at least weekly.

Nonhazardous rodent carcasses are placed in locked red biohazard carts labeled "Sani Pak" to be picked up from FMS and taken to the Sani Pak. Sani Pak equipment consists of a 45-minute cycle of greater than 200°F for 34 minutes and 280°F for 15 minutes, pressure of 38 psi for five minutes and greater than 36.9 psi for seven minutes. Contents are removed by outside contractor and disposed of in the landfill.

Hazardous or infectious agent exposed rodent carcasses are double bagged in red bags and place in locked red biohazard carts labeled Biohazardous and picked up by FMS two times per week. It is picked up by an outside contractor who autoclaves and disposes of contents in the landfill.

**g. Pest Control** [*Guide*, p. 74]

**i.** Describe the program for monitoring and controlling pests (insects, rodents, predators, etc.). Include a description of:

- monitoring devices and the frequency with which devices are checked
- control agent(s) used and where applied, and
- who oversees the program, monitors devices, and/or applies the agent(s).

BVAMC FMS provides pest control and oversight and is responsible for regularly scheduled vermin inspections in all areas. If the use of any insecticide is recommended, the toxicity of the proposed agent(s) will be investigated and approved by the CV. Currently, no insecticides are used in any animal room. Whenever possible, nontoxic agents will be used. If humane traps are needed they will be checked frequently and any animal caught will be humanely euthanized.

**ii.** Describe the use of natural predators (e.g., barn cats) or guard animals (e.g., dogs, donkeys) used for pest and predator control, if applicable.

Not applicable

**iii.** Note how animal users are informed of pesticide use and how animal users may opt out of such use in specific areas.

When non-animal room areas are to be treated, a notice of dates and insecticides to be used is posted on the bulletin board. When an insecticide is to be used in an animal room, all investigators with animals in the room are notified by telephone. If possible, animals are removed from the room being treated. If pesticide use is scheduled, investigators may elect to have their animals removed from animal rooms, or pesticide use may be rescheduled.

**h. Weekend and Holiday Animal Care** [*Guide*, pp. 74-75]

**i.** Describe procedures for providing weekend and holiday care. Indicate who (regular animal care staff, students, part-time staff, etc.) provides and oversees care and what procedures are performed.

Care on weekends and holidays consists of: 1) perform basic sanitation procedures of the VMU, 1) feeding, watering, changing cages when needed and checking the health of all animals in the facility, 2) performing any routine treatment prescribed for sick animals, and 3) recording animal room temperatures, humidity, and population status and results of autoclave quality assurance tests. Emergency phone numbers are posted for ACUP Manager, CV, ACOS, AO, and study personnel and are available for VA Police Service and available at the Administrative Officer of the Day (AOD) desk. One part-time employee works two hours daily on weekends and holidays. Weekend/holiday staff is trained by the ACUP Manager.

**ii.** Indicate qualifications of weekend/holiday staff if not regular staff.

Weekend staff are trained to the same standard as weekly staff by the ACUP manager. Weekend staff have previous experience working with a variety of small animals at the local (b)(6) as a volunteer over the past three years.

**iii.** Describe procedures for contacting responsible animal care and/or veterinary personnel in case of an emergency.

In the event of an emergency, the VMU personnel and VA Police may reach the CV and ACUP Manager by telephone. Telephone numbers are located near telephones and exit doors in the VMU. The CV also provides veterinary medical coverage for weekends and holidays. In his absence, coverage is provided by his associates.

**2. Population Management** [*Guide*, pp. 75-77]

**a. Identification**

Describe animal identification methods for each species (e.g., microchips, cage/tank cards, collars, leg bands, tattoo, ear tags, brands).

All rodents are identified primarily by cage cards. Tattoo equipment for rodent tails and ears is available for individual identification. Rodents may be marked by shaving a small pattern on sides or back, ear-punched or subcutaneous microchip transponder implanted for individual identification. The cage card contains: arrival date, animal identification

number (if any), species, strain, sex, number of animals in cage, age/weight, vendor, investigator name, phone number and protocol number.

**b. Breeding, Genetics, and Nomenclature**

**i.** Describe the program for advising investigators on the selection of animals based on genetic characteristics.

Investigators may seek advice regarding selection of animals based on genetic characteristics from the following sources: a) literature search, b) consultation with other investigators and animal vendors, and c) the CV and ACUP Manager. Information is available on the various websites, and reference materials listed in The Guide may also be useful.

**ii.** Describe the program for advising investigators on using standardized nomenclature to ensure proper reporting of the identification of the research animals with regard to both the strain and sub strain or the genetic background of all animals used in a study.

Investigators are responsible for maintaining the nomenclature of their study animals. Information regarding standard nomenclature may be obtained from reference materials listed in The Guide.

**iii.** Describe genetic management techniques used to assess and maintain genetic variability and authenticity of breeding colonies, including recordkeeping practices (*Guide*, pp. 75-76).

Not applicable- There are no breeding colonies in the VMU at this time.

**iv.** For newly generated genotypes, describe how animals are monitored to detect phenotypes that may negatively impact health and well-being. Note that the methods used to report unexpected phenotypes to the IACUC/OB should be described in section 2.1.B.1.c.ii, "Unexpected Outcomes that Affect Animal Well-Being."

Not applicable

**III. Veterinary Care** [*Guide*, pp. 105-132]
*Note:* Complete each section, including, where applicable, procedures performed in farm settings, field studies, aquatic environments, etc.

**A. Animal Procurement and Transportation** [*Guide*, pp. 106-109; *Ag Guide*, pp. 8; 45; 50-57]

**1. Animal Procurement**
Describe the method for evaluating the quality of animals supplied to the institution (from commercial vendors, other institutions, etc.).

Sources for procuring research animals are carefully selected. Those used must provide animals with documented known health status. Any investigators obtaining animals from noncommercial vendors must consult with the CV. He will then contact the veterinarian at the source and ensure the animals do not pose a risk to others in the facility.

A Certificate of Compliance and Health Certification is enclosed with each order received. Data regarding the disease status of rodents is supplied by Harlan Sprague Dawley, Taconic, National Cancer Institute, Charles River Laboratory and other applicable sources.

The CV is conducting sentinel free routine monitoring using Charles River Lab's PCR technology for screening. A virus panel, bacterial and parasite panel is submitted.

Annual samples are obtained randomly in populations considered " all in/all out ". Biannual sampling will be conducted in chronic populations.

In both cases, 10 specimens are obtained for each panel, consisting of oral swabs for viruses/bacteria; fur swabs for external parasites, and fecal pellets for internal parasites.

Charles River returns the report within two weeks. This mouse surveillance method allows us to determine if our animal census is free from the infectious agents and parasites of concern.

2. **Transportation of Animals**
Describe how animals are transported between outside sources and the institution and within the institution, including loading, unloading, level of biosecurity, immune status and specific pathogen status (consider all species, including aquatic and semi-aquatic species).

The rodents being procured are transported, by air, in specially filtered boxes to the institution. Then a climate-controlled vehicle provided by contractors or vendors bring them to the VMU, (b)(6) Upon arrival, the outside of shipping containers is wiped by the VMU personnel with disinfectant before transporting animals to housing rooms. Animals transported within the facility are transported in their polycarbonate cages. Isolator lids or Chux pads are used to contain any debris during transport. The mice are moved into procedure rooms assigned to the study investigator then returned to animal housing rooms.

## B. Preventive Medicine

1. **Animal Biosecurity** [*Guide*, pp. 109-110]

a. Describe methods used to monitor for known or unknown infectious agents. Note that if sentinel animals are used, specific information regarding that program is to be provided below.

The CV is conducting sentinel free routine monitoring using Charles River Lab's PCR technology for screening. A virus panel, bacterial and parasite panel is submitted.

Annual samples are obtained randomly in populations considered " all in/all out ". Biannual sampling will be conducted in chronic populations.

In both cases, 10 specimens are obtained for each panel, consisting of oral swabs for viruses/bacteria; fur swabs for external parasites, and fecal pellets for internal parasites.

Charles River returns the report within two weeks. This mouse surveillance method allows us to determine our animal census is free from the infectious agents and parasites of concern.

**b.** Describe methods used to control, contain, or eliminate infectious agents.

In general animals are separated by species, source, and health status. Animals are obtained through vendors with a history of providing specifically pathogen free animals. The CV will determine treatment or containment of animals found to be infectious.

**2. Quarantine and Stabilization** [*Guide*, pp. 110-111]

**a.** Describe the initial animal evaluation procedures for each species.

All rodents are examined when transferred from shipping containers to housing cages. Animals are procured from sources that provide animal health status documentation. An incoming animal condition report is generated at the time of the animal's arrival to the facility. Information includes date, investigator, protocol, species, number of animals, vendor, notes on animal's condition, stabilization period and ACUP Manager's and the CV's signature.

**b.** Describe quarantine facilities and procedures for each species. For each species, indicate whether these practices are used for purpose-bred animals, random-source animals, or both.

There are no specific quarantine facilities for purpose-bred species. Procedures include the following: Harlan Sprague Dawley, Taconic, Charles River Laboratory and NCI have a history of providing specifically pathogen-free animals. Prior to receipt of rodents from other sources, health information is reviewed by our CV. All strains of rodents are included in the annual serological monitoring.
In general animals are separated by species, source and health status.

**c.** Describe the required/recommended stabilization period for each species.

The BVAMC VMU has adopted the following stabilization/conditioning guidelines for animals: rodents are acclimated for 72 hours prior to being used in a study. These periods are utilized unless the PI obtains advance IACUC approval.

3. **Separation by Health Status and Species** [*Guide*, pp. 111-112]

   a. Describe the program for the separation of animals by species, source, and health status. If the animals in different status are not maintained separately, describe circumstances in which mixing occurs and explain the rationale for mixing.

   In general, animals are separated by species, source and health status and exposure to potential hazardous agents. Same species of rodents of similar pathogen status may be housed in the same animal holding room depending on available housing space. Animals ordered for the same study but from different vendors may be housed in the same room if of the same health status.

   b. Describe situations where multiple species may be housed in the same room, area, or enclosure.

   Multiple species are not housed in the same room or enclosure.

   c. Describe isolation procedures and related facilities for animals.

   If a contagious illness occurs in rodents the whole room where the ill rodent is will be quarantined. Sick animals will be treated in conventional housing areas or euthanized depending on conditions assessed by the CV.

C. **Clinical Care and Management** [*Guide*, pp. 112-115]

1. **Surveillance, Diagnosis, Treatment and Control of Disease** [*Guide*, pp. 112-113]

   a. Describe the procedure(s) for daily observation of animals for illness or abnormal behavior, including:
   - the observers' training for this responsibility
   - method(s) for reporting observations (written or verbal)
   - method(s) for ensuring that reported cases are appropriately managed in a timely manner.

   The ACUP Manager is responsible for daily observation of animals. Both VMU personnel and study personnel are responsible for reporting sick animals, unusual behavior, etc. The study personnel and VMU personnel have completed web based training in the animal models used in their

ACORP. The PIs are responsible for ensuring the training of the study personnel. The ACUP Manager is responsible for training the VMU personnel. Sick animal reports are written by the VMU personnel or study personnel and submitted to the ACUP Manager. Animals will be evaluated by ACUP Manager and the CV will be contacted if needed.

**b.** Describe methods of communication between the animal care staff and veterinary staff and the researcher(s) regarding ill animals.

The ACUP Manager, CV, PIs, and study personnel primarily communicate via phone especially if sick animals are concerned. Written communication is also conducted with observations and notes left on animal cages or rooms.

The ACUP Manager and the CV also meet in person weekly during the CV's weekly facility visits.

Daily issues including aggression problems, minor injury or questions regarding procedures are communicated to the PI or study personnel by email by the ACUP Manager.

**c.** Describe the preventive medicine and health management/monitoring programs (e.g., physical examination, TB testing, vaccination, hoof/nail trimming, teeth cleaning/floating, vendor surveillance, use of sentinel animals) for each species.

Newly arrived rodents are briefly examined for body condition, injury or abnormalities when transferred into housing cages.
The CV is conducting sentinel free routine monitoring using Charles River Lab's PCR technology for screening. A virus panel, bacterial and parasite panel is submitted.

Annual samples are obtained randomly in populations considered " all in/all out ". Biannual sampling will be conducted in chronic populations.

In both cases, 10 specimens are obtained for each panel, consisting of oral swabs for viruses/bacteria; fur swabs for external parasites, and fecal pellets for internal parasites.

Charles River returns the report within two weeks. This mouse surveillance method allows us to determine our animal census is free from the infectious agents and parasites of concern.

2. **Emergency Care** [*Guide*, p. 114]

   a. Describe the procedures to ensure that emergency veterinary care is continuously available for animals during and outside of regular work hours, including access to drugs or other therapeutics and equipment.

Weekend, holiday and evening emergency coverage is provided on an ongoing basis by the CV or his associate. Contact phone numbers for ACUP Manager and CV are posted inside the VMU exit doors. Weekend, holiday VMU personnel are to call the ACUP Manager first if the CV needs to be contacted.

   b. Describe the authority of the Attending Veterinarian or his/her designee relative to the emergency treatment of animals in the program.

Every attempt is made to contact study personnel when animal issues arise that require veterinary treatment or euthanasia. The CV has access to all animals and resources to manage the veterinary care program and has the authority to act in the best interest of the animals.

3. **Clinical Record Keeping** [*Guide*, p. 115]

   a. Describe the procedure for maintaining medical records and documenting treatment of ill animals including: clinical laboratory findings, diagnoses, treatments, medical progress records, etc. Identify the species for which individual records are maintained and where such records are kept.

Animal issues will be reported to the ACUP Manager who will determine if immediate veterinary attention is warranted. A sick animal report will be initiated for either immediate care or for examination during weekly veterinary visit. The CV is responsible for completing weekly visit sheets and reporting issues to the IACUC. He is also responsible for examining animals on sick animal reports and reporting all pertinent information such as diagnoses, lab tests, treatment, and ensuring VMU personnel maintain records of treatment and progress. Records will be stored in the ACUP

Manager's office, (b)(6), with access restricted to ACUP Manager, the CV or the AO.

**b.** Identify individual(s) (titles, not necessarily names) responsible for maintaining such records and identify where the records are maintained and who, including the IACUC/OB has access to the records.

The ACUP Manager maintains medical records for ill animals needing treatment. The records are kept electronically on the VA server and can be accessed by the AO or ACUP Manager upon the request of IACUC/OB, CV or PI's.

**c.** Describe the role of the Attending Veterinarian in recordkeeping.

The AV confirms documentation of animal reporting records. He ensures the records are current and accurate when he signs a sick animal report document confirming his review of the medical report that is generated. The report is then scanned and kept electronically on the VA network by the ACUP Manager.

**4. Diagnostic Resources.** Describe available diagnostic methods used in the program including:

**a.** In-house diagnostic laboratory capabilities.

The VA does not have any in-house diagnostic laboratory capabilities for animal studies.

**b.** Commercially provided diagnostic laboratory services.

The CV is using Charles River Laboratories to conduct annual screens for viruses, bacteria, and parasites using PCR (Polymerase Chain Reaction). PCR is a molecular biology technology used to amplify a single copy or a few copies of a piece of DNA across several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence.

The CV is conducting sentinel free routine monitoring using Charles River Lab's PCR technology for screening. A virus panel, bacterial and parasite panel is submitted.

Annual samples are obtained randomly in populations considered " all in/all out ". Biannual sampling will be conducted in chronic populations.

In both cases, 10 specimens are obtained for each panel, consisting of oral swabs for viruses/bacteria; fur swabs for external parasites, and fecal pellets for internal parasites.

Charles River returns the report within two weeks. This mouse surveillance method allows us to determine our animal census is free from the infectious agents and parasites of concern.

**c.** Necropsy facilities and histopathology capabilities.

The VMU does have a dedicated Histopathology lab in the facility. The abilities of the lab include a paraffin-embedded center, microtome, and cryostat. Investigators may perform small animal necropsies in VMU small animal procedure rooms or the Histopathology lab.

**d.** Radiology and other imaging capabilities.

Research Service owns and houses an IVIS (In Vivo Imaging System) purchased in 2013 in the VMU. This equipment allows researchers to monitor pathogenesis of infection in animal models without sacrificing animals. This technology allows continuous observation of pathogens, target proteins and specific protein activity during live animal infection. IVIS multimodal imaging provides integrated technology to overlay bioluminescence or fluorescence with an X-ray image that delineates animal anatomy. This offers remarkable potential for researchers to elucidate pathogenic mechanisms of a diverse group of bacterial agents.

## 5. Drug Storage and Control

**a.** Describe the purchase and storage of controlled and non-controlled drugs.

Controlled substances are stored in individual locked boxes in a locked cabinet in a restricted access (b)(6) Keys to the restricted access room cabinet and boxes are kept in individual locked key boxes outside of

the restricted access room. Drug usage is logged, and records maintained by study personnel with the drug in the locked boxes. All controlled substances will be obtained through VA Pharmacy Service and monitored randomly each month by the hospital Controlled Substance Inspection team. Monthly the pharmacy sends a reminder to look for out of date drugs which are then collected and taken to the Pharmacy where they are disposed of according to pharmacy drug disposal policy.
Procedures for ordering, storage and use of controlled substances are outlined in the BVAMC Policy 00-18-11, Controlled Substance Inspection Program. Drugs requiring refrigeration are stored in a locked refrigerator in (b)(6) with restricted access. Non-control drugs are stored in investigator's laboratories or small animal procedure rooms.
Upon completion of an experiment using controlled substances, the remaining controlled substance will be returned with the record of use to the BVAMC pharmacy.
Non-controlled drugs may be obtained from sources other than the VA pharmacy.

**b.** Describe record keeping procedures for controlled substances.

The study personnel maintain records for controlled substance use. Record includes starting volume, date and amount used, study personnel's initials, and remaining amount. The BVAMC Controlled Substances Inspection Team conducts monthly unannounced audits of controlled substances to ensure that record keeping and controlled substance use is in compliance with VA policies. Any discrepancies noted are reported to the investigator, the AO, and the IACUC. Only the AO and the ACUP Manager have access to individual lock boxes to facilitate monthly audits.

## D. Surgery [*Guide*, pp. 115-123]

### 1. Pre-Surgical Planning [*Guide*, p. 116]

Describe the process(es) used to ensure adequate pre-surgical planning, including: identifying personnel; locating equipment, supplies, veterinary involvement for selecting analgesic and anesthetic agents and facilities; planning; and pre- and post-operative care.

No major surgeries or survival surgeries are being conducted at the BVAMC.

Minor surgeries such as rodent surgical procedures in order to obtain tissue or organ harvest after euthanasia are conducted.

For these minor surgeries the PI explains in the ACORP, the protocols, supplies and staff that will be conducting these procedures. The CV reviews the protocols regarding surgical aspects, anesthetics, and analgesic use, and ensures personnel competencies to perform procedures in the animal use form.

2. **Surgical Facilities** [*Guide*, pp. 116-117, 144-145]
List building name(s) and room number(s) or other locations (coded, if confidential) where surgical procedures are performed. For each, describe:
   - the type of species (including rodents, fish, agricultural species, etc.)
   - nature of procedure(s) (major/minor/emergency, survival and non-survival, etc.)
   - the amount of use [heavy (daily), moderate (weekly), or light]
   - major surgical support equipment available (gas anesthesia machines, respirators, surgical lights, etc.)
   - facilities for aseptic surgery, surgical support, animal preparation, surgeon's scrub, operating room, and postoperative recovery
   - construction features of the operating room(s), including interior surfaces, ventilation, lighting, and fixed equipment used to support surgical procedures and other means of enhancing contamination control

*Note*: If preferred, the information requested in this section may be provided in Table.

(b)(6) currently has no activity taking place in this room.

(b)(6) small animal procedure (b)(6) may be used for rodent surgical procedures. All rooms are used minimally, light.

(b)(6) may also be used for rodent surgical procedures. Past use has been primarily minor surgical procedures and tissues harvest after euthanasia.

All rooms are designed with stainless steel counter tops for sanitization of surfaces. (b)(6) houses an anesthesia machine for use by PIs. (b)(6)

has lighting fixtures for surgical procedures and an anesthesia machine owned by a VA investigator.

3. **Surgical Procedures** [*Guide*, pp. 117-118]

   a. Describe the criteria used to differentiate major from minor survival surgery, including classification for certain procedures (e.g., laparoscopic technique).

   Not applicable.
   Neither major nor minor survival surgery is being conducted at the BVAMC.

   b. How is non-survival surgery defined?

   Not applicable.

4. **Aseptic Technique** [*Guide*, pp. 118-119]

   a. Describe procedures, equipment, and protective clothing used for aseptic surgery. Include patient and surgeon preparation.

   Not Applicable

   b. Describe methods used to sterilize instruments and protective clothing, including a description of approved liquid sterilants and instrument exposure time(s) required for each, if applicable.

   For minor non-survival surgeries to harvest tissue and/or organs, instrument packs are autoclaved with sterilization indicators to assure materials are sufficiently sterilized. Sterile disposable lab coats and gloves are used. A hot glass bead sterilizer is utilized for re-sterilization of instruments during procedures making sure instruments have cooled sufficiently to minimize risk of burns to animals. The hot glass bead sterilizer is used for small instrument sterilization. Glass beads reach a minimum temperature of 450°F. Instruments must stand 15 seconds to one minute to achieve sterilization.

   c. Describe methods for instrument re-sterilization between serial surgeries.

   A hot glass bead sterilizer is utilized for re-sterilization of instruments

during procedures making sure instruments have cooled sufficiently to minimize risk of burns to animals. The hot glass bead sterilizer is used for small instrument sterilization. Glass beads reach a minimum temperature of 450°F. Instruments must stand 15 seconds to one minute to achieve sterilization.

**d.** Indicate how effectiveness of sterilization is monitored.

Not applicable. Currently not doing any survival surgeries.

**e.** Describe surgical support functions provided by the program to investigators.

The program provides the following surgical support functions to investigators:
-Access to and scheduling of surgery and procedure rooms and limited equipment
-Enrollment in the Occupational Health and Safety Program
-VMU Animal and Safety Training
-Use of autoclave, VA core owned table top inhalation rodent anesthesia system
-The consultant veterinarian
-Pre-surgical functions such as initial reviews of ACORPs for Biosafety Subcommittee and IACUC reviews

**5. Intraoperative Monitoring** [*Guide*, p. 119]
Describe monitoring and recording requirements for each species, including the type of record(s) maintained. Also note monitoring of anesthesia during non-survival procedures.

Monitoring of rodents during non-survival surgeries are conducted as described in individual study ACORPs by qualified study personnel.

**6. Postoperative Care** [*Guide*, pp. 119-120]
Describe the postoperative care program, including who is responsible for overseeing and providing the care, types of records maintained (e.g., perioperative), where the records are maintained, etc.

Not Applicable.

**E. Pain and Distress** [*Guide*, pp. 120-121]

1. Describe how and by whom pain and distress are assessed.

The animals are assigned pain categories in the animal ACORP form by the PI in consultation with the CV during initial review of the ACORP. When an animal use form is submitted to the IACUC, the PI must document if procedures will cause more than momentary pain and distress. If so, procedures and methods that will be used to minimize pain and distress must be stated and described. If animals will not receive pain relief it must be scientifically justified in the ACORP. A scoring sheet for individual animals is developed by the investigator and used by the monitoring study personnel that includes body weight, diarrhea, alopecia, rough hair coat, hunched posture, lethargy, coughing or labored breathing, nasal discharge, jaundice or anemia, neurological disturbances, bleeding, self-induced trauma and tumor size ulceration necrosis or infection as appropriate for the individual study criteria. Scoring ranges from zero (none) to five (severe). Any indication of pain or distress in housing conditions observed by animal care technicians is promptly reported to the ACUP Manager. When needed, the CV is consulted and the investigator contacted. The individual animal's status is evaluated and a decision is made by the PI, the CV and/or ACUP Manager regarding removal of the animal from the study or euthanasia. A copy of the evaluation form used is available in the SOP.

2. Describe training programs for personnel responsible for monitoring animal well-being, including species-specific behavioral manifestations as indicators of pain and distress.

Personnel will be trained utilizing a combination of resources including, CITI training modules, CV, PI, ACUP manager, and The Guide.

**F. Anesthesia and Analgesia** [*Guide*, pp. 121-123]

1. List the agents used for each species.
*Note:* If preferred, this information may be provided in Table or additional Appendix.

Mouse - isoflurane, buprenorphine, lidocaine/bupivacaine, carprofen.

2. Describe how the veterinarian provides guidance and advice to researchers concerning choice and use of anesthetics, analgesics or other pain moderating methods.

The CV provides consultation regarding anesthesia and analgesia use during the study design and initial review of the ACORP. Drugs and dosages chosen to have been determined to be safe and approved for use and meets clinical and humane requirement and suits the needs of individual studies. A competency assessment for study personnel is performed by the CV.

3. Describe the monitoring of the effectiveness of analgesics, including who does the monitoring. Include in the description any non-pharmacologic means used to diminish pain and distress.

Anesthetic and analgesic use is monitored by the investigator, the study personnel, and overseen by the CV. Study personnel are trained through CITI courses, the PI, or CV prior to initiating work with animals.
When the ACORP is approved by the IACUC committee, the IACUC may appoint monitors not participating in the study to periodically monitor the condition of the animals and report back to the IACUC. VMU personnel regularly evaluate animals. If there are pain and distress related concerns or issues they may be presented to the CV and he may consult with the PI to ensure pain and distress issues are adequately addressed. If needed, a modification will be submitted to the IACUC ensuring appropriate procedures and policies are being followed for animal care.

4. Describe how the veterinarian(s) and the IACUC/OB evaluate the proposed use of neuromuscular blocking agent to ensure the well-being of the animal.

Not applicable.
There are currently no ACORPs using neuromuscular blocking agents.

5. Describe policies and practices for maintaining and ensuring function of equipment used for anesthesia.

Anesthesia equipment is to be operated and maintained according to manufacturer's recommendations. The rodent anesthesia system activated charcoal absorption filters will be weighted prior to each use and weight

recorded on canisters. Canisters will be discarded after 50 grams of total added weight. A yearly maintenance/calibration contract is in place.

**G. Euthanasia** [*Guide*, pp. 123-124]

1. Describe approved methods of euthanasia, including humane slaughter (for additional guidance, see pertinent AAALAC Reference Resources). Include:
   - consideration of species, age, condition (e.g., gestational period, or neonatal) and
   - location(s) for the conduct of the procedure.

   *Note:* If preferred, this information may be provided in Table or additional Appendix.

Methods used in approved ACORPs for euthanasia are consistent with the AVMA Panel on Euthanasia, 2007. Generally chemical agent use is preferable to physical methods unless scientifically justified. Euthanasia methods used in individual ACORPS are based on the species used, animal age and scientific objectives of the study and on providing rapid loss of consciousness and death with little or no pain or distress. The method must be reliable and irreversible and suitable to maintaining research study scientific objectives. The CV provides input or advice regarding appropriate euthanasia methods during initial review of the ACORP. There is a specific area in the ACORP that details euthanasia use. Animals will be euthanized by qualified and proficient personnel in a professional and humane manner. A secondary method such as exsanguination or thoracotomy may be used to ensure the death of the animal. Euthanasia will be performed in procedure or lab rooms only and not in animal housing rooms to prevent distress to other animals because of vocalization or pheromones.
Animals currently euthanized in the VMU are rodents.

2. Describe policies and practices for maintaining and ensuring function of equipment used for euthanasia.

Rodent anesthesia systems will be maintained according to manufacturer's recommendations. An annual maintenance/calibration contract is in place. Euthanasia procedures are performed as stated in individual ACORPs.

3. Describe the methods used to confirm death of an animal.

Euthanasia will only be performed by qualified individuals who are trained to

recognized signs of cessation of the vital signs in the species used. A secondary method that is irreversible such as exsanguation or thoracotomy may also be used to ensure death.

## IV. Physical Plant [*Guide*, pp. 133-155]

### A. Facilities Overview

Provide a brief introduction to the animal housing and use facilities. Note that this overview should augment the information provided in **Appendix 2** (Summary of Animal Housing and Support Sites), which includes area, average daily census, and person responsible for each site. Please use consistent terminology for the buildings/areas/sites described in the Location section of the Appendix. Please do not repeat information, but supplement the descriptions provided elsewhere to assist the reviewers understanding of the interaction between facilities, special housing locations, and separate procedural areas.

The ACUP Manager is responsible for the daily operation of the VMU, (b)(6) (b)(6) That includes animal husbandry duties and animal welfare, facility sanitation and maintenance, submission of work orders to ensure proper facility functions, procurement of supplies and materials, overall safety, and supervision of VMU personnel and oversight of study personnel. The ACUP Manager reports any issues to the AO/R&D when they arise. The ACUP Manager works closely with numerous services including FMS to ensure smooth operation and maintenance of the facility. She works with Bio-Med for equipment issues and the Safety Office, the Industrial Hygienist, the Chemical Safety Coordinator, and other hospital staff in materials, acquisitions and supplies, logistics and the sterile processing distribution unit for timely procurement of supplies.

### B. Centralized (Centrally-Managed) Animal Facility(ies)

In this section, describe each centralized or centrally-managed animal housing and use facility. Include in **Appendix 3** the floor plans of each on 8.5" x 11" or A4 paper. Ensure that the drawings are legible and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.). Note that a separate section for describing "satellite housing areas" is included below.

Separately describe **each** Location or Animal Facility, addressing each of the features outlined below (1-8). A complete description of each must be provided; however,

common features among locations or facilities may be indicated as such and do not need to be repeated.

1. General arrangement of the animal facilities (conventional, clean/dirty corridor, etc.).
2. Physical relationship of the animal facilities to the research laboratories where animals may be used.
3. Types of available animal housing spaces used, such as conventional, barrier, isolation/quarantine, hazard containment (infectious, radioactive, chemical), "animal cubicles" or facilities specifically designed for housing certain species such as ponds, pastures, feedlots, etc.
4. Finishes used throughout the animal facility for floors, walls, ceilings, doors, alleyways, gates, etc. (note any areas that are not easily sanitized and describe how these are maintained).
5. Engineering features (design, layout, special HVAC systems, noting exhaust air treatment, if applicable) used in hazardous agent containment.
6. Security features, such as control of entry, perimeter fences, gates, entryways, cameras, guards; identify and describe exceptions for individual facilities or areas incorporating fewer or additional security features than the general features described.
7. Consideration for facilities with exterior windows, if applicable, including management of environmental conditions (i.e., temperature and photoperiod control) and potential security risks.
8. Storage areas for flammable or hazardous agents and materials (e.g., disinfectants, cage-washing chemicals, pesticides, fuel).

The VMU is located in building (b)(6) BVAMC in a (b)(6). One animal housing area is arranged in a cluster of four animal rooms opening into an exclusive corridor and separated from the main clean corridor by a noise lock. Two animal housing areas are separated into two housing areas: 1) two rooms opening into an exclusive corridor, separated from the main corridor by a single door, and 2) four animal rooms opening into an exclusive corridor and one (1) room opening into another animal room separated from the main corridor by a single door. All rooms housing animals are under conventional conditions. Animals are not housed in laboratory space. Every effort will be made to satisfy the scientific aims of the ACORP by manipulating lighting, temperature or humidity in individual animal rooms as needed.

Research labs where animals may be used are within the VMU (b)(6)
Exclusive research lab rooms are (b)(6)

Boise VMU is a dedicated facility utilized for the research of small animals such as rodents. Currently this is the only animal that is housed in this facility.

Finishes: VMU corridor walls are concrete, masonry block and painted with high-gloss alkyd enamel. Floors are concrete, sealed with epoxy paint. Tubular 1 l/2" diameter, aluminum bumper rails are placed along all corridors in animal portion of VMU to protect all walls and corners. Wall to cement floor junctions are sloped to facilitate cleaning. All VMU doors are equipped with steel frames to prevent damage to walls.

The doors are all 3'6" wide and 7'0" high. Four animal holding room doors open into the room. Six animal holding room doors open into the animal holding corridor and one animal room opens into another animal room. All doors are metal and have a small 10" x 10" view window, with the bottom of the window being 4'10" from the base of the door.

Ceilings are composed of two layers of 5/8" waterproof gypsum wallboard and painted with high gloss alkyd enamel.

Engineering features of the building is a dedicated HVAC system with 100% fresh air. Air leaving animal rooms is filtered.

Security features are monitored 24 hours a day, 7 days a week by alarmed entries and exits. A keyless card scan system with code is used to gain access into the building. If the system alarms and is not justified promptly the on-site Police respond to investigate the occurrence. There are two main entries to the building and two additional exits all tied into the alarm systems.
Exterior Windows: None of the animal rooms have exterior windows. The Offices do and the windows are tied into the alarm system for the building.

Storage Areas with chemicals used for cleaning are primarily stored in (b)(6) janitorial closet. The VMU staff are the only persons to have access to this room. All containers are stored with dates on bottles and inside bins to contain potential leaks. A single barrel of Cage Klenz is utilized in the dirty room for the cage washer.

**C. Satellite Animal Housing Facilities**

In addition to the Appendices summarizing Heating, Ventilation, and Air-Conditioning (**Appendix 11**) and Lighting Systems (**Appendix 16**), summarize animal housing areas that are not centrally-managed or maintained in (**Appendix 17**), "Satellite Animal Housing Areas."

1. Describe the criteria used to determine/define a "Satellite Animal Housing Area," which may include remote housing facilities or laboratories temporarily or consistently housing animals.

Not Applicable-BVAMC has no satellite animal housing facilities.

2. Describe the process used by the IACUC/OB to authorize, provide oversight of, and ensure compliance with *Guide* standards for the housing of animals outside of centrally-maintained facilities. Include a description of Attending Veterinarian access and physical security.

Not Applicable

**D. Emergency Power and Life Support Systems**

*Note:* Complete a Heating, Ventilation, and Air-Conditioning (HVAC) Summary (**Appendix 11**) and Lighting Summary (**Appendix 16**) for each Location described in the Summary of Animal Housing and Support Sites (**Appendix 2**).

1. **Power** [*Guide*, p. 141]

For each Location, Centralized Animal Facility, and Satellite Housing Facility, provide a brief description of the following:

- Availability of emergency power and if so, what electrical services and equipment are maintained in the event the primary power source fails.
- History of power failures, noting frequency, duration, and, if emergency power was not available, steps taken to ensure the comfort and well-being of the animals present and the temperature extremes reached in animal rooms during the failure.

An emergency generator specifically for the VMU was installed in January 2003 and is tested monthly to ensure proper operation. Conversion to emergency power is less than three (3) minutes. Electrical Service to animal housing, HVAC and heating, and most electrical outlets by the generator is maintained. The generator is powered by diesel fuel with an adequate supply for thirty-seven (37) hours.

Power failure history has been minimal and only for short durations. The emergency generator is tested monthly and has operated as expected with no adverse effect to the animal facility. In the event of loss of power to the facility for an extended period, the emergency/disaster plan will be followed. This may include covering animal racks with blankets in case of heat loss and possibly relocating animals to interior rooms to minimize extreme temperature fluctuation. Research has purchased four oil filled heaters that can be used in individual animal housing rooms to maintain heat in the event of a system failure.
If electrical power is operating, fans may also be obtained from FMS to use in individual animal rooms in the event of high temperature extremes.

2. **Other System Malfunctions.** If not previously reported, describe animal losses or health problems resulting from power, HVAC, or other life support system (e.g., individually ventilated cages) failures, and mechanisms for reporting such incidences. AAALAC International Rules of Accreditation (Section 2.f).

Not Applicable – None to report.

**E. Other Facilities** [*Guide*, pp. 144, 150]

1. **Other Animal Use Facilities** [*Guide*, pp. 146-150]
Describe other facilities such as imaging, irradiation, and core/shared behavioral laboratories or rooms. Include a description of decontamination and methods for preventing cross-contamination in multi-species facilities.

Not Applicable-BVAMC has no other animal use facilities.

2. **Other Animal Program Support Facilities**
Describe other facilities providing animal care and use support, such as feedmills, diagnostic laboratories, abattoirs, etc.

Not Applicable-BVAMC has no other animal support facilities.

According to the privacy principles on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, we wish to advise you that the personal data in the Program Description will become part a permanent file owned by AAALAC International, and that can be shared with AAALAC International offices and representatives in order to perform an evaluation of the institution's animal care and use program and provide accreditation services. The institution has the option of exercising rights of data access, rectification, cancellation, and opposition at:

(b)(6)

# Appendix 1: Glossary of Abbreviations and Acronyms

Please provide a Table defining abbreviations and acronyms used in this Program Description.

## Abbreviations

| | |
|---|---|
| ACUP Manager | Animal Care and Use Program Manager |
| AO | Administrating Officer- Joanne Mitten |
| ASISTS | Automated Safety Incident Surveillance Tracking System |
| AWE | Annual Workplace Evaluation |
| BioMed | Biomedical |
| BVAMC | Boise Veterans Affairs Medical Center |
| °C | Degrees Centigrade |
| CDC | Centers for Disease Control and Prevention |
| CSA | Common Services Architecture |
| CV | Consulting Veterinarian |
| EOC | Environment of Care |
| EOCC | Environment of Care Committee |
| °F | Degrees Fahrenheit |
| FMS | Facilities Management Service |
| GEMS | Green Environment Management System |
| GFCI | Ground Fault Circuit Interrupter |
| HEPA | High Efficiency Particulate Arrestance |

# Appendix 1: Glossary of Abbreviations and Acronyms

| | |
|---|---|
| HPIC | Histology, Pathology Imaging Core Facility |
| IACUC | Institutional Animal Care and Use Committee |
| IBC | Institutional Biosafety Committee |
| IDLH | Immediate Danger to Life and Health |
| IH | Industrial Hygienist |
| IVREF | Idaho Veterans Research and Education Foundation |
| L | Liter |
| MCM | Medical Center Memorandum |
| N95 | A type of respirator |
| N100 | Specialized respirator |
| NFPA | National Fire Protection Agency |
| OSHA | Occupational Safety and Health Administration |
| PI | Principal Investigator |
| PPE | Personal Protective Equipment |
| R&D | Research and Development |
| REL | Recommended Exposure Limit |
| SDS | Safety Data Sheet |
| SOP | Standard Operating Procedures |
| SRS | Subcommittee on Research Safety |
| TMS | Talent Management System |
| UV | Ultraviolet |
| VA | Veterans Affairs |

# Appendix 1: Glossary of Abbreviations and Acronyms

| | |
|---|---|
| VHA | Veterans Health Administration |
| VISN | Veterans Integrated Service Network |
| VMU | Veterinary Medical Unit |

# Appendix 2: Summary of Animal Housing and Support Sites

Briefly summarize in the following Table the animal facility or facilities, noting the number of areas in which animals are housed (buildings, floors, farms, satellite housing facilities, etc.), the total square footage/metres (or acreage) for animal care and use, and the total square footage/metres (or acreage) for necessary support of the animal care and use program covered by this Description (water treatment plant/area if housing aquatic or amphibian species, cagewashing facilities, service corridors, etc. and additional areas to be considered are enumerated in the *Guide*). Detailed information for satellite housing facilities is requested in Appendix 17. Include only one line entry for satellite housing facilities in this table to provide the total square footage for all satellite housing areas listed in appendix 17. If more than one facility/site, note the approximate distance (yards/miles or meters/kilometers) to each facility from a reference point such as from the largest animal facility. A campus/site map (with a distance scale) may be included as an additional Appendix (Appendix 2.1) to provide this information. See Instructions, Addendum A - Animal Facility Square Footage/Meters Compilation Form for guidance in calculating the size of your animal care and use program.

| | Animal Housing and Support Sites | | | | | |
|---|---|---|---|---|---|---|
| Location (building/site/farm name*) | Distance from main facility (campus/site map(s) also may be provided in lieu of this information) | Approx. sq.ft./m (acreage) animal housing | Approx. sq.ft./m (acreage) support/ procedure space | Species housed | Approximate Daily Animal Census by species | Person in charge of site |
| Veterinary Medical Unit, (b)(6) | (b)(6) | 1,024 sq. ft. | - | Mice | 1 mouse daily average | ACUP Manager, Administrative Officer |
| | | | | | | |
| Veterinary Medical Unit, (b)(6) | (b)(6) | - | 5,682 sq. ft. | Mice | 1 mouse daily average | ACUP Manager, Administrative Officer |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| Totals: | | 1,024 sq. ft. | 5,682 sq. ft. | [redacted] | | |
| Total animal housing and support space: | | 6,706 sq. ft. Please specify $ft^2$ or $m^2$ | | | | |

[a]Please state name and/or use acronyms described in **Appendix 1** for building names, if not coded for confidentiality.
[b]Campus or site map(s) may also be provided in lieu of this information.

# Appendix 3: Line Drawings

Provide floor plans of each centralized animal housing facility. Plans should be provided on 8.5" x 11" or A4 paper. Ensure that the drawings are legible, including room numbers if used, and the use of each room is indicated (animal housing, procedure room, clean cage storage, hazardous waste storage, etc.) either directly on the drawing or in a Key/Table.

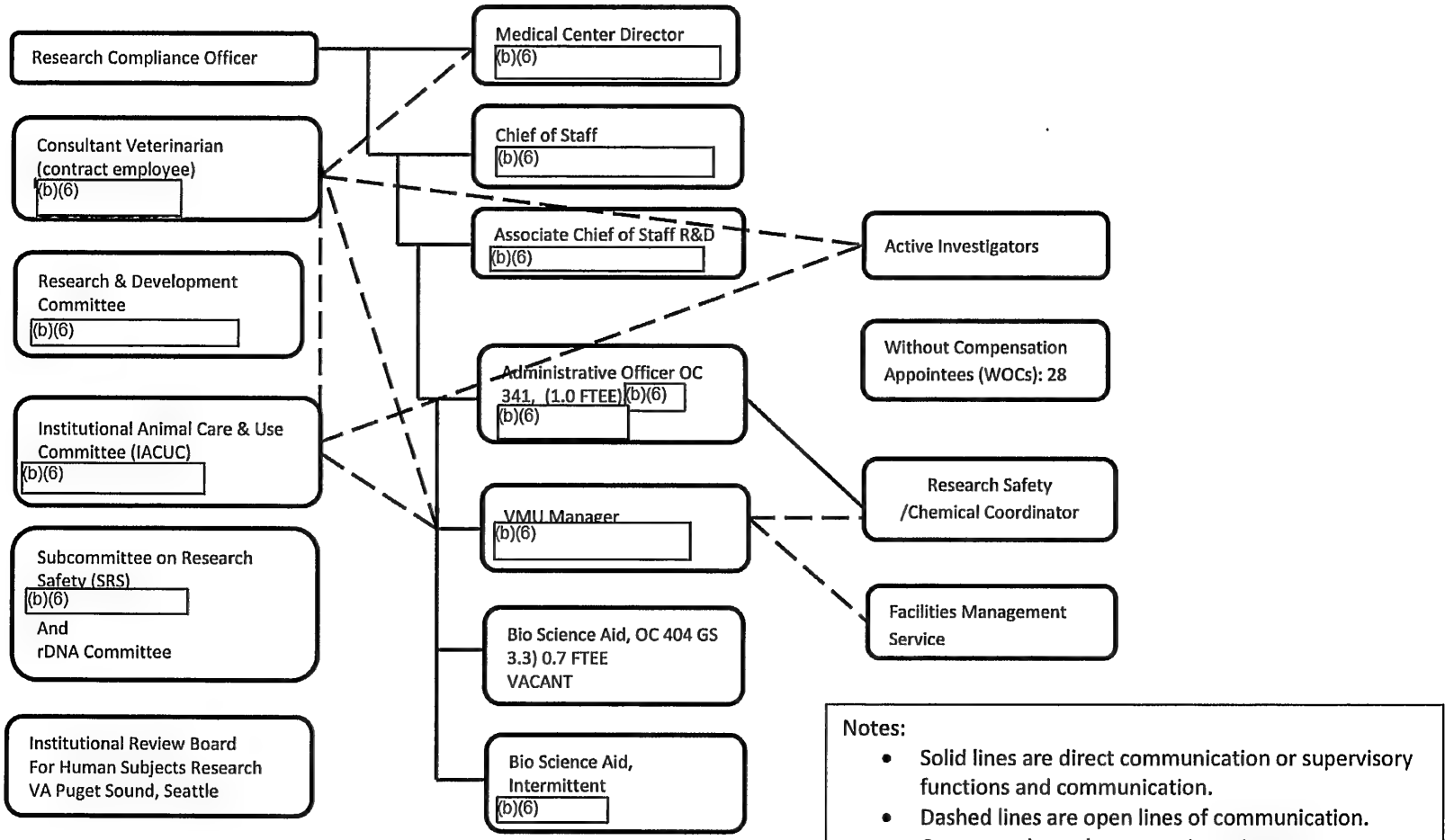
## Appendix 3: Line Drawings

See Attachment for Information- #1

# Appendix 4: Organizational Chart(s)

Provide an accurate, current, and detailed organization chart or charts that detail the lines of authority from the Institutional Official to the Attending Veterinarian, the IACUC/OB, and personnel providing animal care. If applicable, include personnel responsible for managing satellite housing areas/locations and depict the reporting relationship between the Attending Veterinarian and other(s) having a direct role in providing veterinary care.

# Appendix 4: Organizational Chart(s)




Notes:

- Solid lines are direct communication or supervisory functions and communication.
- Dashed lines are open lines of communication.
- Correspondence (e.g., meeting minutes, recommendations, reports, etc.) from the IACUC to the IO may be routed through administrative channels for informational purposes.

# Appendix 5: Animal Usage

In order to assist the site visitors in their evaluation of the animal care and use program, please provide the information requested below. Information should be provided for all animals approved for use in research, teaching or testing, including those which may be used or housed in laboratories outside the animal care facility. Of particular interest is information on those animals which are used in research projects involving recovery surgical procedures, behavioral or other testing requiring chairing or other forms of restraint, or exposure to potentially hazardous materials. An alternate format is acceptable as long as the information requested is provided.

| Project/Protocol Title | IACUC/OB Number | Principal Investigator | Species | Total Number of Animals Approved | Pain & Distress Category (1) | Special Considerations (use checkmark if applicable) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | SS (2) | MSS (3) | FFR (4) | PR (5) | HAU (6) | NCA (7) |
| (b)(6) | (b)(6) | (b)(6) | Mouse | 899 | D | | | | | X | |
| | | | | | | | | | | | |
| (b)(6) | (b)(6) | (b)(6) | Mouse | 331 | D | | | | | X | |
| | | | | | | | | | | | |
| (b)(6) | (b)(6) | (b)(6) | Mouse | 145 | D | | | | | X | |

# Appendix 5: Animal Usage

| Project/Protocol Title | IACUC/OB Number | Principal Investigator | Species | Total Number of Animals Approved | Pain & Distress Category (1) | Special Considerations (use checkmark if applicable) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | SS (2) | MSS (3) | FFR (4) | PR (5) | HAU (6) | NCA (7) |
| (b)(6) | | | | | | | | | | | |
| (b)(6) | (b)(6) | (b)(6) | Hamster | 576 | D | | | | | X | |
| (b)(6) | (b)(6) | (b)(6) | Mouse | 479 | D | | | | | X | |
| (b)(6) | (b)(6) | (b)(6) | Mice | 8 | D | | | | | X | |

(1) If applicable, please provide a description / definition of any pain/distress classification used within this Appendix in the space below. If pain/distress categories are not used, leave blank.
(2) Survival Surgery (SS)
(3) Multiple Survival Surgery (MSS)
(4) Food or Fluid Regulation (FFR)
(5) Prolonged Restraint (PR)
(6) Hazardous Agent Use (HAU)

# Appendix 5: Animal Usage

(7) Non-Centralized Housing and/or Procedural Areas (NCA), i.e., use of live animals in any facility, room, or area that is not directly maintained or managed by the animal resources program, such as investigator laboratories, department-managed areas, teaching laboratories, etc.

Pain/Distress Classification Description/Definition, if applicable:

| |
|---|
| |

In the Table below, provide an approximate annual usage for all species:

| Animal Type or Species | Approximate Annual Use |
|---|---|
| Mice | 240 |
| | |
| | |

| Animal Type or Species | Approximate Annual Use |
|---|---|
| | |
| | |
| | |

[Create additional rows by pressing TAB in the bottom-right box.]

# Appendix 6: Personnel Medical Evaluation Form

Provide a ***blank*** copy of form(s) used by medically-trained personnel to review individual health assessment, individual risk assessment, health history evaluation, health questionnaire, periodic medical evaluation, etc. If form(s) are not used, include a description of how such evaluations are performed in the Program Description (Section 2.I.A.2.b.ii.1).d), Section 2 (Description). I (Animal Care and Use Program). A (Program Management). 2 (Personnel Management). b (Occupational Health and Safety or Personnel). ii (Standard Working Conditions and Baseline Precautions). 1) (Medical Evaluation and Preventive Medicine for Personnel). d).

## Animal Exposure Baseline History

1. Name: _____ Social Security Number (Last 4): _____
2. Date of Birth: _____ ☐ Male ☐ Female ☐ Pregnant?
3. Service: _____ Job Title: _____
4. Extension: _____ Pager: _____ E-mail: _____
5. Routing Symbol: _____ Building and Room #: _____
6. Supervisor's Name: _____ Phone: _____
7. Animal contact within VA Medical Center (check all that apply):

☐ Dogs ☐ Swine ☐ Mice ☐ Cats
☐ Sheep ☐ Hamsters ☐ Nonhuman Primates
☐ Goats ☐ Gerbils ☐ Rabbits ☐ Guinea Pigs
☐ Rats ☐ Other: _____

8. Have you ever contracted a disease from animals, or experienced an animal-related injury (including bites, scratches, needle sticks, etc.)? ☐ Yes ☐ No

If yes, please describe:

_____

_____

9. Please check all of the activities that apply:

- ☐ Direct hands-on work with animals
- ☐ Work with unfixed animal tissues/fluids
- ☐ No direct contact, enter animal facility but do not enter animal holding rooms
- ☐ No direct contact, but enter animal holding rooms
- ☐ No direct contact, but work on ventilation system, including changing filters

10. Total amount of contact time with animals (include contact with animal tissues, waste, body fluids, carcasses, or animal quarters):

- ☐ More than one hour/week
- ☐ One or less hour/week
- ☐ Other (explain): _____

11. Does your work with animals involve any human or animal pathogens or infectious diseases?

☐ Yes ☐ No

If yes, please list pathogens or diseases: _____

_____

12. If you are in contact with nonhuman primates:

a. Have you ever had tuberculosis (TB)? ☐ Yes ☐ No

If yes, please list medications and how long you took them: _____

_____

b. Have you been immunized with Bacillus Calmette-Guerin (BCG) for TB?

☐ Yes ☐ No Year: _____

c. Have you ever had a positive reaction to a TB test (Tine Test, PPD, Tuberculin Skin Test)? ☐ Yes ☐ No

If yes, please name any medications you took and the length of time you took them.

_____

_____

# Appendix 6: Personnel Medical Evaluation Form

13. Are you receiving immunosuppressive therapy such as prednisone, steroids, or anti-cancer drugs? ☐ Yes ☐ No

14. How often do you wear personal protective equipment when working with animals?
(Check the appropriate responses.)

| Type of PPE | Sometimes | Always | Never | Rarely |
|---|---|---|---|---|
| Gloves | ☐ | ☐ | ☐ | ☐ |
| Gown | ☐ | ☐ | ☐ | ☐ |
| Mask | ☐ | ☐ | ☐ | ☐ |
| Cap | ☐ | ☐ | ☐ | ☐ |
| Goggles/Glasses | ☐ | ☐ | ☐ | ☐ |

15. Do you smoke, eat, or drink in the animal areas? ☐ Yes ☐ No

16. How often do you do the following after handling animals at work?

| | Sometimes | Always | Never | Rarely |
|---|---|---|---|---|
| Wash Hands | ☐ | ☐ | ☐ | ☐ |
| Change Clothing | ☐ | ☐ | ☐ | ☐ |
| Shower | ☐ | ☐ | ☐ | ☐ |

17. Do you have a history of the following conditions? (Check those you have or have had.)

☐ Hay fever ☐ Asthma ☐ Allergic Skin Problems ☐ Eczema
☐ Sinusitis ☐ Other Chronic Respiratory Infections

18. Has anyone in your family ever had hay fever, asthma, eczema, or allergic skin problems?

☐ Yes ☐ No

19. Do you have sneezing spells, runny or stuffy nose, watery or itchy eyes, coughing, wheezing, or shortness of breath, skin rash or hives, or difficulty swallowing after working with laboratory animals or their cages? (Circle those above you have.)

20. Which animals cause the above problems? _____

_____

# Appendix 6: Personnel Medical Evaluation Form

21. How frequently are you bothered by the symptoms below?

| Symptoms | | Never | Monthly | Weekly | Daily |
|---|---|---|---|---|---|
| Watery, itchy eyes | ☐ | ☐ | ☐ | ☐ | |
| Runny or stuffy nose | ☐ | ☐ | ☐ | ☐ | |
| Sneezing spells | | ☐ | ☐ | ☐ | ☐ |
| Frequent, dry cough | ☐ | ☐ | ☐ | ☐ | |
| Wheezing in chest | ☐ | ☐ | ☐ | ☐ | |
| Rash or hives | ☐ | ☐ | ☐ | ☐ | |
| Shortness of breath | ☐ | ☐ | ☐ | ☐ | |
| Trouble swallowing | ☐ | ☐ | ☐ | ☐ | |

22. Do you have any house pets? ☐ Yes ☐ No

If yes, what type of animals do you have? _____

23. Do you have any symptoms with your pets? ☐ Yes ☐ No

If yes, what type of symptoms do you have? _____

24. Do you have a chronic respiratory disease? ☐ Yes ☐ No

If yes, please explain: _____

25. Have you ever had a hernia (rupture)? ☐ Yes ☐ No

If yes, please explain: _____

26. Have you ever had back trouble or pain that required treatment, surgery, or loss of time at work? ☐ Yes ☐ No

If yes, please explain: _____

27. Do you have joint problems or any form of arthritis? ☐ Yes ☐ No

If yes, please describe: _____

28. Do you work with chemicals? ☐ Yes ☐ No

# Appendix 6: Personnel Medical Evaluation Form

Do you have symptoms from the chemicals? ☐ Yes ☐ No

Comments: _____

29. Please note any other health history you consider significant:

_____

30. Immunization/TB Screening History:

| Immunization/Test | Date | Side Effect/Reaction | Other |
|---|---|---|---|
| Tetanus (most recent) | _____ | _____ | _____ |
| Rabies Series, Initial | _____ | _____ | _____ |
| Rabies Booster | _____ | _____ | _____ |
| Rabies Immune Globulin | | _____ | _____ _____ |
| Hepatitis B Series, Initial | _____ | _____ | _____ |
| Hepatitis B, 2nd Series | _____ | _____ | _____ |
| Tuberculin Skin Test | _____ | _____ | _____ |
| Other | _____ | _____ | _____ |
| Chest X-ray | _____ | _____ | _____ |

Signature of Employee: _____ Date: _____

Print Name: _____

Signature of Interviewer: _____ Date: _____

Print Name: _____

# Appendix 6: Personnel Medical Evaluation Form

## Employment Hazardous Drug Exposure Questionnaire

**The following questionnaire is specific to individuals who handle hazardous drugs, as outlined within the job description.**

**NOTE: Hazardous Drugs as defined by NIOSH 2014 or subsequent updates**

| Today's Date | Day | Month | Year |
|---|---|---|---|
| | | | |

| Name | Last | First | M.I. \|ID# - - \| |
|---|---|---|---|
| | | | |

**Spouse's Occupation**

**Employment History**

**Present Employment (Please check appropriate response for primary employment):**

| | |
|---|---|
| ☐ Hospital-Oncology Inpatient Unit | ☐ Oncology Pharmacy |
| ☐ Hospital-Oncology Outpatient Unit | ☐ Hospital Pharmacy |
| ☐ Hospital-Med/Surg Inpatient Unit | ☐ Veterinary Office |
| ☐ Hospital-Med/Surg Outpatient Unit | ☐ Other, Specify: |

**Job or Occupation:**

| | |
|---|---|
| ☐ Staff Nurse | ☐ Pharmacist |
| ☐ Head Nurse/Asst. Head Nurse | ☐ Pharmacy Technician/Pharmacy Intern |
| ☐ Clinical Nurse Specialist | ☐ Physician |
| ☐ Nurse Practitioner | ☐ Veterinary Personnel |
| ☐ Environmental Services | ☐ Other, Specify |

# Appendix 6: Personnel Medical Evaluation Form

| (Housekeeping) | | | |
|---|---|---|---|
| | | | |
| **When did you start you current job?** | | **Month** | **Year** |
| **What shift do you usually work? How long is the shift?** | | | |
| Shift | No. of hours | Shift | No. of hours |
| Day | | Night | |
| Evening | | Weekends | |

| **Reproductive History** | | |
|---|---|---|
| **Please check appropriate responses as it pertains to your employment at this company:** | | |
| Difficulty conceiving a child?* | ☐ Yes | ☐ No |
| Consulted physician for reproductive problem?* | ☐ Yes | ☐ No |
| Miscarriage or stillbirth of a child?* | ☐ Yes | ☐ No |
| Deformity of a child?* | ☐ Yes | ☐ No |
| Menstrual Irregularities?* | ☐ Yes | ☐ No |
| *If Yes, Please Explain: | | |

| **Hazardous Drug Exposure History** |
|---|
| **Work History Section** |
| How long have you been involved in the, preparation, handling, or administration of hazardous drugs or cleaning of spills or patient rooms? |

# Appendix 6: Personnel Medical Evaluation Form

| Weeks: | Months: | Years: | |
|---|---|---|---|

# Appendix 6: Personnel Medical Evaluation Form

| In the course of your employment, **while handling hazardous drugs or while working near others who were working with hazardous drugs**, have you ever had any of the following?<br>*Please check the appropriate box for each symptom listed below:* | | | | |
|---|---|---|---|---|
| **Symptoms** | | **< 1-2 times per month** | **1-2 times per week** | **Almost Daily** |
| **Abdominal pain** | | | | |
| **Anorexia** | | | | |
| **Bruising** | | | | |
| **Constipation** | | | | |
| **Diarrhea** | | | | |
| **Dizziness** | | | | |
| **Esophagitis** | | | | |
| **Facial flushing** | | | | |
| **Fever** | | | | |
| **Hair loss** | | | | |
| **Headache** | | | | |
| **Malaise** | | | | |
| **Nausea** | | | | |
| **Nose bleed** | | | | |

# Appendix 6: Personnel Medical Evaluation Form

| | | | | |
|---|---|---|---|---|
| **Respiratory** | | | | |
| **Skin rash** | | | | |
| **Sore throat** | | | | |
| **Vomiting** | | | | |
| **Weight loss (unplanned)** | | | | |
| **Wheezing** | | | | |
| **Other (Specify):** | | | | |
| **NOTE: Hazardous Drugs as defined by NIOSH 2014 or subsequent updates.** | | | | |

| **Hazardous Drug Exposure Section** | | | | |
|---|---|---|---|---|
| Have you ever accidentally ingested, breathed in, or had skin contact with a hazardous drug?<br>(think of spills, splashes, cuts, needle sticks)<br>☐ Yes ☐ No; not to my knowledge If No, skip to next section. | | | | |
| **If yes, how often in your career?** | | | | |
| ☐ Once or twice | ☐ 3-5 times | ☐ 5-10 times | ☐ Other (please specify ) | |
| **Occurred during (check all that apply)** | | | | |
| ☐Mixing/ preparation | ☐Administration | ☐Receiving or delivery | ☐Cleaning a spill | Other (please specify) |
| Any known reactions or symptoms? If Yes, please describe: | | | | |

# Appendix 6: Personnel Medical Evaluation Form

| Personal Protection Section | | | | | | |
|---|---|---|---|---|---|---|
| ***Please check the most appropriate answer as it applies to handling hazardous drugs.*** | | | | | | |
| | **Always** | **Often** | **Sometimes** | **Rarely** | **Never** | **Not Provided by Employer** |
| I wear disposable gloves | | | | | | |
| I wear double gloves | | | | | | |
| I change my gloves according to the guidelines on my unit | | | | | | |
| I wear disposable gowns | | | | | | |
| I wear eye protection (goggles) | | | | | | |
| I wear a protective mask | | | | | | |
| I wear disposable booties | | | | | | |
| I wear disposable hair covers | | | | | | |
| When preparing hazardous drugs, I use a biological safety cabinet or an isolator | | | | | | |
| When preparing hazardous drugs, I use a closed system transfer device (CSTD) | | | | | | |
| When administering hazardous drugs, I use a CSTD | | | | | | |
| When disposing of administered doses I wear the required PPE | | | | | | |

# Appendix 6: Personnel Medical Evaluation Form

| | | | | | | |
|---|---|---|---|---|---|---|
| When cleaning a hazardous drug spill I wear the appropriate PPE | | | | | | |
| I know where Hazardous Drug Spill Kits are located | | | | | | |
| **NOTE: Hazardous Drugs, as defined by NIOSH 2014 or subsequent updates.** | | | | | | |

Adapted from: National Institute for Occupational Safety and Health (NIOSH), Employment Hazardous Drug Exposure Questionnaire (unpublished) 2010.

## Occupational Safety and Health Administration (OSHA)
## Respirator Medical Evaluation Questionnaire (Mandatory)

**(Appendix C to Section 1910.134)**

(Note to the Employer: Answers to questions in Section 1, and to question 9 in Section 2 of Part A do not require a medical examination.)

To the Employee: Can you read? (circle one): Yes No

Your employer must allow you to answer this questionnaire during normal working hours, or at a time and place that is convenient to you. To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the health care professional who will review it.

**Part A - Section 1. (Mandatory)** The following information must be provided by every employee who has been selected to use any type of respirator (PLEASE PRINT).

1. Today's date: _____
2. Your name: _____
3. Your age (to nearest year): _____

# Appendix 6: Personnel Medical Evaluation Form

4. Sex: ☐ Male ☐ Female

5. Your height: _____ ft. _____ in.

6 Your weight: _____lbs.

7. Your job title: _____

8. A phone number where you can be reached by the health care professional who reviews this questionnaire (include the area code): _____.

9. The best time to phone you at this number: _____ ☐ AM ☐ PM

10. Has your employer told you how to contact the health care professional who will review this questionnaire? (circle one): ☐ Yes ☐ No

11. Check the type of respirator you will use (you can check more than one category):

    a. ☐ N, R, or P disposable respirator (filter-mask, non-cartridge type only).

    b. ☐ Other type (for example, half- or full-facepiece type, powered-air purifying, supplied-air, self-contained breathing apparatus).

12. Have you worn a respirator? (circle one): ☐ Yes ☐ No

If yes, what type(s): _____.

**Part A - Section 2. (Mandatory)** Questions 1 through 9 below must be answered by every employee who has been selected to use any type of respirator.

1. Do you currently smoke tobacco or have you smoked tobacco in the last month?
   ☐ Yes ☐ No

2. Have you ever had any of the following conditions?

| | | | |
|---|---|---|---|
| a. | Seizures (fits) | ☐ Yes | ☐ No |
| b. | Diabetes (sugar disease) | ☐ Yes | ☐ No |
| c. | Allergic reactions that interfere with your breathing | ☐ Yes | ☐ No |
| d. | Claustrophobia (fear of closed-in places) | ☐ Yes | ☐ No |

# Appendix 6: Personnel Medical Evaluation Form

e. Trouble smelling odors ☐ Yes ☐ No

3. Have you ever had any of the following pulmonary or lung problems?

a. Asbestosis ☐ Yes ☐ No
b. Asthma ☐ Yes ☐ No
c. Chronic Bronchitis ☐ Yes ☐ No
d. Emphysema ☐ Yes ☐ No
e. Pneumonia ☐ Yes ☐ No
f. Tuberculosis ☐ Yes ☐ No
g. Silicosis ☐ Yes ☐ No
h. Pneumothorax (collapsed lung) ☐ Yes ☐ No
i. Lung Cancer ☐ Yes ☐ No
j. Broken ribs ☐ Yes ☐ No
k. Any chest injuries or surgeries ☐ Yes ☐ No
l. Any other lung problem that you have been told about ☐ Yes ☐ No

4. Do you currently have any of the following symptoms of pulmonary or lung illness?

a. Shortness of breath ☐ Yes ☐ No
b. Shortness of breath when walking fast on level ground or walking up a slight hill or incline ☐ Yes ☐ No
c. Shortness of breath when walking with other people at an ordinary pace on level ground ☐ Yes ☐ No
d. Have to stop for breath when walking at your own pace on level ground ☐ Yes ☐ No
e. Shortness of breath when washing/dressing yourself ☐ Yes ☐ No
f. Shortness of breath that interferes with your job ☐ Yes ☐ No
g. Coughing that produces phlegm (thick sputum) ☐ Yes ☐ No
h. Coughing that wakes you early in the morning ☐ Yes ☐ No
i. Coughing that occurs mostly when you are lying down ☐ Yes ☐ No
j. Coughing up blood in the last month ☐ Yes ☐ No
k. Wheezing ☐ Yes ☐ No
l. Wheezing that interferes with your job ☐ Yes ☐ No
m. Chest pain when you breathe deeply ☐ Yes ☐ No
n. Any other symptoms that you think may be related to lung problems ☐ Yes ☐ No

# Appendix 6: Personnel Medical Evaluation Form

5. Have you ever had any of the following cardiovascular or heart problems?

a. Heart attack ☐ Yes ☐ No
b. Stroke ☐ Yes ☐ No
c. Angina ☐ Yes ☐ No
d. Heart failure ☐ Yes ☐ No
e. Swelling in your legs or feet (not caused by walking) ☐ Yes ☐ No
f. Heart arrhythmia (heart beating irregularly) ☐ Yes ☐ No
g. High blood pressure ☐ Yes ☐ No
h. Any other heart problem that you have been told about ☐ Yes ☐ No

6. Have you ever had any of the following cardiovascular or heart symptoms?

a. Frequent pain or tightness in your chest ☐ Yes ☐ No
b. Pain or tightness in your chest during physical activity ☐ Yes ☐ No
c. Pain or tightness in your chest that interferes with your job ☐ Yes ☐ No
d. In the past 2 years, have you noticed your heart skipping or missing a beat ☐ Yes ☐ No
e. Heartburn or indigestion that is not related to eating ☐ Yes ☐ No
f. Any other symptoms that you think may be related to heart or circulation problems ☐ Yes ☐ No

7. Do you currently take medication for any of the following problems?

a. Breathing or lung problems ☐ Yes ☐ No
b. Heart trouble ☐ Yes ☐ No
c. Blood pressure ☐ Yes ☐ No
d. Seizures (fits) ☐ Yes ☐ No

8. If you've used a respirator, have you ever had any of the following problems? (If you've never used a respirator, check here _____ and go to question 9.)

a. Eye irritation ☐ Yes ☐ No
b. Skin allergies or rashes ☐ Yes ☐ No
c. Anxiety ☐ Yes ☐ No
d. General weakness or fatigue ☐ Yes ☐ No
e. Any other problem that interferes with your use of a respirator

☐ Yes ☐ No

9. Would you like to talk to the health care professional who will review this questionnaire about your answers to this questionnaire? ☐ Yes ☐ No

Questions 10 to 15 below **must** be answered by every employee who has been selected to use either a full-facepiece respirator or a self-contained breathing apparatus (SCBA). For employees who have been selected to use other types of respirators, answering these questions is voluntary.

10. Have you ever lost vision in either eye (temporarily or permanently)? ☐ Yes ☐ No

11. Do you currently have any of the following vision problems?

a. Wear contact lenses ☐ Yes ☐ No
b. Wear glasses ☐ Yes ☐ No
c. Color blind ☐ Yes ☐ No
d. Any other eye or vision problem ☐ Yes ☐ No

12. Have you ever had an injury to your ears, including a broken eardrum? ☐ Yes ☐ No

13. Do you currently have any of the following hearing problems?

a. Difficulty hearing ☐ Yes ☐ No
b. Wear a hearing aid ☐ Yes ☐ No
c. Any other hearing or ear problem ☐ Yes ☐ No

14. Have you ever had a back injury? ☐ Yes ☐ No

15. Do you currently have any of the following musculoskeletal problems?

a. Weakness in either of your arms, hands, legs or feet ☐ Yes ☐ No
b. Back pain ☐ Yes ☐ No
c. Difficulty fully moving your arms and legs ☐ Yes ☐ No
d. Pain or stiffness when you lean forward or backward at the waist ☐ Yes ☐ No
e. Difficulty fully moving your head up or down ☐ Yes ☐ No

f. Difficulty fully moving your head side to side ☐ Yes ☐ No
g. Difficulty bending at your knees ☐ Yes ☐ No
h. Difficulty squatting to the ground ☐ Yes ☐ No
i. Difficulty climbing a flight of stairs or a ladder carrying more than 25 lbs. ☐ Yes ☐ No
j. Any other muscle or skeletal problem that interferes with using a respirator ☐ Yes ☐ No

**Part B** - Any of the following questions, and other questions not listed, may be added to the questionnaire at the discretion of the health care professional who will review the questionnaire.

1. In your present job, are you working at high altitudes (over 5,000 feet) or in a place that has lower than normal amounts of oxygen? ☐ Yes ☐ No

If yes, do you have feelings of dizziness, shortness of breath, pounding in your chest, or other symptoms when you're working under these conditions? ☐ Yes ☐ No

2. At work or at home, have you ever been exposed to hazardous solvents, hazardous airborne chemicals (e.g., gases, fumes, or dust), or have you come into skin contact with hazardous chemicals? ☐ Yes ☐ No

If yes, name the chemicals, if you know them. _____

_____

_____

3. Have you ever worked with any of the materials, or under any of the conditions, listed below?

a. Asbestos ☐ Yes ☐ No
b. Silica (e.g., in sandblasting) ☐ Yes ☐ No
c. Tungsten/Cobalt (e.g., grinding or welding this material) ☐ Yes ☐ No
d. Beryllium ☐ Yes ☐ No
e. Aluminum ☐ Yes ☐ No
f. Coal (for example, mining) ☐ Yes ☐ No
g. Iron ☐ Yes ☐ No
h. Tin ☐ Yes ☐ No

i. Dusty environments ☐ Yes ☐ No
j. Any other hazardous exposures ☐ Yes ☐ No

If yes, describe these exposures: _____

_____

4. List any second jobs or side businesses you have: _____

_____

5. List your previous occupations: _____

_____

6. List your current and previous hobbies: _____

_____

7. Have you been in the military services? ☐ Yes ☐ No

If yes, were you exposed to biological or chemical agents (either in training or combat)? ☐ Yes ☐ No

8. Have you ever worked on a hazardous material (HAZMAT) team? ☐ Yes ☐ No

9. Other than medications for breathing and lung problems, heart trouble, blood pressure, and seizures mentioned earlier in this questionnaire, are you taking any other medications for any reason (including over-the-counter medications)? ☐ Yes ☐ No

If yes, name the medications if you know them.

_____

10. Will you be using any of the following items with your respirator(s)?

a. High-efficiency particulate air (HEPA) filters ☐ Yes ☐ No
b. Canisters (for example, gas masks) ☐ Yes ☐ No
c. Cartridges ☐ Yes ☐ No

11. How often are you expected to use the respirator(s)? (check Yes or No for all answers that apply to you.)

a. Escape only (no rescue) ☐ Yes ☐ No
b. Emergency rescue only ☐ Yes ☐ No
c. Less than 5 hours per week ☐ Yes ☐ No
d. Less than 2 hours per day ☐ Yes ☐ No
e. 2 to 4 hours per day ☐ Yes ☐ No
f. Over 4 hours per day ☐ Yes ☐ No

12. During the period you are using the respirator(s), is your work effort:

a. Light (less than 200 kcal per hour) ☐ Yes ☐ No

If yes, how long does this period last during the average shift?

_____hrs. _____mins.

*[Examples of a light work effort are sitting while writing, typing, drafting, or performing light assembly work; or standing while operating a drill press (1-3 lbs.) or controlling machines.]*

b. Moderate [200 to 350 kilocalories (kcal) per hour] ☐ Yes ☐ No

If yes, how long does this period last during the average shift?

_____hrs. _____mins.

*[Examples of moderate work effort are sitting while nailing or filing; driving a truck or bus in urban traffic; standing while drilling, nailing, performing assembly work, or transferring a moderate load (about 35 lbs.) at trunk level; walking on a level surface about 2 mph or down a 5-degree grade about 3 mph; or pushing a wheelbarrow with a heavy load (about 100 lbs.) on a level surface.]*

c. Heavy (above 350 kcal per hour) ☐ Yes ☐ No

If yes, how long does this period last during the average shift?

_____hrs. _____mins.

*[Examples of heavy work are lifting a heavy load (about 50 lbs.) from the floor to your waist or shoulder; working on a loading dock; shoveling; standing while bricklaying or chipping castings; walking up an 8-degree grade about 2 mph; climbing stairs with a heavy load (about 50 lbs.).]*

# Appendix 6: Personnel Medical Evaluation Form

13. Will you be wearing protective clothing and/or equipment (other than the respirator) when using your respirator? ☐ Yes ☐ No

If yes, describe this protective clothing and/or equipment: _____

_____

14. Will you be working under hot conditions (temperature exceeding 77° F)? ☐ Yes ☐ No

15. Will you be working under humid conditions? ☐ Yes ☐ No

16. Describe the work you will be doing while using your respirator(s):

_____

_____

17. Describe any special or hazardous conditions you might encounter when using your respirator(s) (e.g., confined spaces, life-threatening gases): _____

_____

18. Provide the following information, if you know it, for each toxic substance you'll be exposed to when using your respirator(s):

Name of the first toxic substance: _____

Estimated maximum exposure level per shift: _____

Duration of exposure per shift: _____

Name of the second toxic substance: _____

Estimated maximum exposure level per shift: _____

Duration of exposure per shift: _____

Name of the third toxic substance: _____

Estimated maximum exposure level per shift: _____

# Appendix 6: Personnel Medical Evaluation Form

Duration of exposure per shift: _____

The name of any other toxic substances you'll be exposed to while using your respirator:

_____

_____

_____

19. Describe any special responsibilities you will have while using your respirator(s) that may affect the safety and well-being of others (e.g., rescue, security).

_____

_____

_____

20. Have you gained or lost 10 pounds or more in the last year?
☐ Yes ☐ No

21. Have you had dental procedures with tooth removal or prostheses in the last year?
☐ Yes ☐ No

22. Have you had jaw surgery in the last year? ☐ Yes ☐ No

23. Have you used a respirator with a tight-fitting facepiece, such as an N95 or HEPA, in the last 6 months at work? ☐ Yes ☐ No

24. When were you last fit-tested for the respirator you are currently using? _____

Do you wish to be fit-tested? ☐ Yes ☐ No

## Periodic Medical Questionnaire

(This or Equivalent Acute/Current Medical Elements are Mandatory)

Part 2 (1910.1001 Appendix D)

# Appendix 6: Personnel Medical Evaluation Form

This Part 2 includes the abbreviated Periodic Medical Questionnaire, which must be administered to all employees who are provided periodic medical examinations under the medical surveillance provisions of the standard.

## I. General

1. Name _____
2. Social Security Number _____
3. Present Occupation _____
4. Facility _____
5. Address _____

   (City/State/Zip Code) _____
6. Telephone Number _____
7. Interviewer _____
8. Date _____
9. Date of Birth (Month/Day/Year) _____
10. Place of Birth _____
11. Sex Male ☐ Female ☐
12. Marital Status Single ☐ Married ☐ Widowed ☐ Separated/Divorced ☐

# Appendix 6: Personnel Medical Evaluation Form

## II. Occupational History

1. Have you ever worked full time (30 hours per week or more) for 6 months or more? Yes ☐ No ☐

If yes, have you ever worked for a year or more in any dusty job? Yes ☐ No ☐

Was dust exposure: Mild ☐ Moderate ☐ Severe ☐

Specific job/industry _____ Total Years Worked _____

2. Have you ever been exposed to gas or chemical fumes in your work? Yes ☐ No ☐

Was the exposure: Mild ☐ Moderate ☐ Severe ☐

Specific job/industry _____ Total Years Worked _____

3. What has been your usual occupation or job (the one you have worked at the longest)?

Job occupation _____

Number of years employed _____

Position/Job Title _____

Business/Field/Industry _____

## III. Recent Medical History

1. Do you consider yourself to be in good health? Yes ☐ No ☐

If no, state reason: _____

# Appendix 6: Personnel Medical Evaluation Form

2. Are you suffering from or have you ever suffered from:
   a. Epilepsy (or fits, seizures, convulsions)? Yes ☐ No ☐
   b. Rheumatic fever? Yes ☐ No ☐
   c. Kidney disease? Yes ☐ No ☐
   d. Bladder disease? Yes ☐ No ☐
   e. Diabetes? Yes ☐ No ☐
   f. Jaundice? Yes ☐ No ☐
   g. Cancer? Yes ☐ No ☐
3. If you get a cold, does it usually go to your chest (usually means more than ½ the time)? Yes ☐ No ☐ Do not get colds ☐
4. During the past year, have you had any chest illnesses that have kept you off work, indoors at home, or in bed? Yes ☐ No ☐

   If yes, did you produce phlegm with any of these chest illnesses? Yes ☐ No ☐

   In the last year, how many such illnesses (with increased phlegm) did you have that lasted a week or more? Number of illnesses _____ No such illnesses ☐
5. In the past year, have you had any of the following?

   **Yes or No - Further Comment on Positive Answer**

   a. Asthma? Yes ☐ No ☐ Comment: _____
   b. Bronchitis? Yes ☐ No ☐ Comment: _____
   c. Hay Fever? Yes ☐ No ☐ Comment: _____
   d. Other Allergies Yes ☐ No ☐ Comment: _____
   e. Pneumonia? Yes ☐ No ☐ Comment: _____
   f. Tuberculosis? Yes ☐ No ☐ Comment: _____

g. Chest Surgery? Yes ☐ No ☐ Comment: _____

h. Other Lung Problems? Yes ☐ No ☐ Comment: _____

i. Heart Disease? Yes ☐ No ☐ Comment: _____

j. Frequent Colds? Yes ☐ No ☐ Comment: _____

k. Chronic Cough? Yes ☐ No ☐ Comment: _____

l. Shortness of Breath (when walking or climbing one flight of stairs)? Yes ☐ No ☐
Comment: _____

6. Do you:

a. Wheeze Yes ☐ No ☐

b. Cough up phlegm Yes ☐ No ☐

c. Smoke cigarettes Yes ☐ No ☐ If yes: _____ Packs per day _____ How many years?

Signature: _____ Date: _____

## Formaldehyde Exposure Medical Questionnaire

1910.1048 Appendix D

Employee Occupational Health History Interview Regarding Formaldehyde Exposure

**A. Identification**

Date: _____

Employee Name: _____

Social Security Number: _____

Birthdate: _____ Age: _____ Sex: _____

Height: _____ Weight: _____

# Appendix 6: Personnel Medical Evaluation Form

Facility: _____

Job Title: _____

**B. Medical History**

1. Have you ever been in the hospital as a patient? Yes ☐ No ☐

   If yes, what kind of problem were you having? _____

   _____

2. Have you ever had any kind of operation? Yes ☐ No ☐

   If yes, what kind? _____

   _____

3. Do you take any kind of medicine regularly? Yes ☐ No ☐

   If yes, what kind? _____

4. Are you allergic to any drugs, foods, or chemicals? Yes ☐ No ☐

   If yes, what kind of allergy is it? _____

   _____

   What causes the allergy? _____

   _____

5. Have you ever been told that you have asthma, hay fever, or sinusitis? Yes ☐ No ☐
6. Have you ever been told that you have emphysema, bronchitis, or any other respiratory problems? Yes ☐ No ☐
7. Have you ever been told you had hepatitis? Yes ☐ No ☐
8. Have you ever been told that you had cirrhosis? Yes ☐ No ☐
9. Have you ever been told that you had cancer? Yes ☐ No ☐

# Appendix 6: Personnel Medical Evaluation Form

10. Have you ever had arthritis or joint pain? Yes ☐ No ☐
11. Have you ever been told that you had high blood pressure? Yes ☐ No ☐
12. Have you ever had a heart attack or heart trouble? Yes ☐ No ☐

**C. Medical History Update**

1. Have you been in the hospital as a patient any time within the past year? Yes ☐ No ☐

   If so, for what condition? _____

   _____

2. Have you been under the care of a physician during the past year? Yes ☐ No ☐

   If so, for what condition? _____

   _____

3. Is there any change in your breathing since last year? Yes ☐ No ☐

   Better? _____ Worse? _____ No change? _____

   If change, do you know why? _____

4. Is your general health different this year from last year? Yes ☐ No ☐

   If different, in what way? _____

5. Have you in the past year or are you now taking any medication on a regular basis?
   Yes ☐ No ☐

   Name Medication: _____

   Condition being treated: _____

# Appendix 6: Personnel Medical Evaluation Form

## D. Occupational History

1. How long have you worked for your present employer? _____

2. What jobs have you held with this employer? Include job title and length of time in each job.

_____

_____

_____

3. In each of these jobs, how many hours a day were you exposed to chemicals? _____

4. What chemicals have you worked with most of the time?

_____

_____

5. Have you ever noticed any type of skin rash you feel was related to your work?
   Yes ☐ No ☐

6. Have you ever noticed that any kind of chemical makes you cough? Yes ☐ No ☐

   Any chemical that makes you wheeze? Yes ☐ No ☐

   Become short of breath or cause your chest to become tight? Yes ☐ No ☐

7. Are you exposed to any dust or chemicals at home? Yes ☐ No ☐

   If yes, explain: _____

8. In other jobs, have you ever had exposure to:

| | | |
|---|---|---|
| Wood dust? | Yes ☐ | No ☐ |
| Nickel or chromium? | Yes ☐ | No ☐ |
| Silica (foundry, sand blasting)? | Yes ☐ | No ☐ |
| Arsenic or asbestos? | Yes ☐ | No ☐ |
| Organic solvents? | Yes ☐ | No ☐ |
| Urethane foams? | Yes ☐ | No ☐ |

# Appendix 6: Personnel Medical Evaluation Form

**E. Occupational History Update**

1. Are you working on the same job this year as you were last year? Yes ☐ No ☐

   If not, how has your job changed? _____

   _____

2. What chemicals are you exposed to on your job? _____

   _____

3. How many hours a day are you exposed to chemicals? _____

4. Have you noticed any skin rash within the past year that you feel was related to your work?
   Yes ☐ No ☐

   If yes, explain circumstances: _____

5. Have you noticed that any chemical makes you cough, be short of breath or wheeze?
   Yes ☐ No ☐

   If yes, can you identify it? _____

**F. Miscellaneous**

1. Do you smoke? Yes ☐ No ☐

   If so, how much and for how long? _____

   Pipe _____ Cigars _____ Cigarettes _____

2. Do you drink alcohol in any form? Yes ☐ No ☐

   If so, how much, how long, and how often? _____

3. Do you wear glasses or contact lenses? Yes ☐ No ☐

4. Do you get any physical exercise other than that required to do your job? Yes ☐ No ☐

   If so, explain: _____

5. Do you have any hobbies or "side jobs" that require you to use chemicals, such as furniture stripping, sand blasting, insulation, or manufacture of urethane foam, furniture, etc.?
   Yes ☐ No ☐

   If so, please describe, giving type of business or hobby, chemicals used, and length of exposures.

   _____

   _____

**G. Symptoms Questionnaire**

1. Do you ever have any shortness of breath? Yes ☐ No ☐

   If yes, do you have to rest after climbing several flights of stairs? Yes ☐ No ☐

   If yes, if you walk on a level surface with people your own age, do you walk slower than they do? Yes ☐ No ☐

   If yes, if you walk slower than a normal pace, do you have to limit the distance that you walk? Yes ☐ No ☐

   If yes, do you have to stop and rest while bathing or dressing? Yes ☐ No ☐

2. Do you cough as much as 3 months out of the year? Yes ☐ No ☐

   If yes, have you had this cough for more than 2 years? Yes ☐ No ☐

   If yes, do you ever cough anything up from chest? Yes ☐ No ☐

3. Do you ever have a feeling of smothering, or tightness in your chest, or are unable to take a deep breath? Yes ☐ No ☐

   If yes, do you notice this on any particular day of the week? Yes ☐ No ☐

   If yes, what day of the week? Yes ☐ No ☐

   If yes, do you notice that this occurs at any particular place? Yes ☐ No ☐

   If yes, do you notice that this is worse after you have returned to work after being off for several days? Yes ☐ No ☐

4. Have you ever noticed any wheezing in your chest? Yes ☐ No ☐

   If yes, is this only with colds or other infections? Yes ☐ No ☐

Is this caused by exposure to any kind of dust or other material? Yes ☐ No ☐

If yes, what kind? _____

5. Have you noticed any burning, tearing, or redness of your eyes when you are at work?
   Yes ☐ No ☐

   If so, explain circumstances: _____

   _____

6. Have you noticed any sore or burning throat or itchy or burning nose when you are at work?
   Yes ☐ No ☐

   If so, explain circumstances: _____

   _____

7. Have you noticed any stuffiness or dryness of your nose? Yes ☐ No ☐
8. Do you ever have swelling of the eyelids or face? Yes ☐ No ☐
9. Have you ever been jaundiced? Yes ☐ No ☐

   If yes, was this accompanied by any pain? Yes ☐ No ☐
10. Have you ever had a tendency to bruise easily or bleed excessively? Yes ☐ No ☐
11. Do you have frequent headaches that are not relieved by aspirin or Tylenol?
    Yes ☐ No ☐

    If yes, do they occur at any particular time of the day or week? Yes ☐ No ☐

    If yes, when do they occur? _____
12. Do you have frequent episodes of nervousness or irritability? Yes ☐ No ☐
13. Do you tend to have trouble concentrating or remembering? Yes ☐ No ☐
14. Do you ever feel dizzy, light-headed, and excessively drowsy or like you have been drugged? Yes ☐ No ☐

# Appendix 6: Personnel Medical Evaluation Form

15. Does your vision ever become blurred? Yes ☐ No ☐
16. Do you have numbness or tingling of the hands or feet or other parts of your body?
    Yes ☐ No ☐
17. Have you ever had chronic weakness or fatigue? Yes ☐ No ☐
18. Have you ever had any swelling of your feet or ankles to the point where you could not wear your shoes? Yes ☐ No ☐
19. Are you bothered by heartburn or indigestion? Yes ☐ No ☐
20. Do you ever have itching, dryness, or peeling and scaling of the hands? Yes ☐ No ☐
21. Do you ever have a burning sensation in the hands or reddening of the skin?
    Yes ☐ No ☐
22. Do you ever have cracking or bleeding of the skin on your hands? Yes ☐ No ☐
23. Are you under a physician's care? Yes ☐ No ☐

    If yes, for what are you being treated?: _____
24. Do you have any physical complaints today? Yes ☐ No ☐

    If yes, explain: _____
25. Do you have other health conditions not covered by these questions? Yes ☐ No ☐

    If yes, explain: _____

# Appendix 6: Personnel Medical Evaluation Form



*Enclosure 3-3*

## Latex Allergy Questionnaire

1 Have you had any problems with the skin on your hands? ☐Yes ☐No
If yes, describe:_____

_____

2. Were you seen by a healthcare provider for this problem? ☐Yes ☐No
If yes, what did the healthcare provider diagnose? _____

_____

3. What treatment was recommended? _____

_____

4. Are you still under the care of this provider? ☐Yes ☐No

5. What makes your symptoms worse?_____

6. What makes your symptoms better?_____

7. What do you wash your hands with? (List name brands)_____

_____

8. What do you apply to your hands? ___Oil-Based Lotions ___Water-Based Lotions
___Barrier Creams ___Medications ___nothing
If any checked, list name brands:_____

9. Do you have any skin symptoms elsewhere on your body? ☐Yes ☐No
If yes, please describe: _____

10. Does the skin on your hands:

| | | | | | |
|---|---|---|---|---|---|
| Get red? | ☐Yes | ☐No | Get dry? | ☐Yes | ☐No |
| Burn? | ☐Yes | ☐No | Thicken? | ☐Yes | ☐No |
| Itch? | ☐Yes | ☐No | Peel? | ☐Yes | ☐No |
| Hurt? | ☐Yes | ☐No | Crust? | ☐Yes | ☐No |

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# Appendix 6: Personnel Medical Evaluation Form



| | | | | | |
|---|---|---|---|---|---|
| Sting? | ☐Yes | ☐No | Swell? | ☐Yes | ☐No |
| Tingle? | ☐Yes | ☐No | Get hives? | ☐Yes | ☐No |
| Crack? | ☐Yes | ☐No | Get clustered bumps? | ☐Yes | ☐No |
| Bleed? | ☐Yes | ☐No | Blisters or vesicles? | ☐Yes | ☐No |
| Scab? | ☐Yes | ☐No | Get spaced bumps? | ☐Yes | ☐No |

11. What type of gloves were you wearing when your symptoms occurred?

☐ Powdered Latex ☐ Non-Powdered Latex
☐ Powdered Vinyl ☐ Non-Powdered Vinyl
☐ Powdered Nitryl ☐ Non-Powdered Nitryl
☐ Powdered Other ☐ Non-Powdered other
☐ Other_____

12. What type of gloves are you wearing now?

State type and name brand:_____

13. Have your symptoms persisted? ☐Yes ☐No

14. How many times do you change gloves per day, approximately?

☐ 1-5 ☐ 6-10 ☐ 11-20 ☐ >20

15. How long do you wear each pair of gloves on average?

☐ < 5 min. ☐ 6-15 min. ☐ < 1 hr ☐ 1-2 hrs ☐ > 2 hrs

16. What allergies do you have? _____

17. Does your parents have allergies? ☐ One ☐ Both ☐ Neither

18. Have you had surgery, delivered a baby, had major dental work or any other invasive medical procedure? ☐Yes ☐No

If yes, please give dates. (It is not necessary to list the procedures.)_____

_____

19. Have you ever had eczema (atopic dermatitis) of the hands? ☐Yes ☐No

20. Do any family members have asthma? ☐Yes ☐No

# Appendix 6: Personnel Medical Evaluation Form



21. Do you have sinus problems, other than seasonal pollen-related problems?
☐Yes ☐No

22. Do you have problems with conjunctivitis (eye inflammation or infections)?
☐Yes ☐No

23. Have you ever had an anaphylactic (allergic shock) reaction? ☐Yes ☐No
If yes, describe: _____

24. Have you ever experienced swelling or itching of the lips when blowing up balloons?
☐Yes ☐No

25. Have you ever experienced swelling or itching of the mouth after dental exams?
☐Yes ☐No

26. Have you experienced hives, itching of the lips or throat or more severe symptoms when you've eaten or handled any of the following: (Please check as appropriate):

| | | | |
|---|---|---|---|
| ☐ Apple | ☐ Apricot | ☐ Avacado | ☐ Banana |
| ☐ Carrot | ☐ Celery | ☐ Cherry | ☐ Chestnut |
| ☐ Fig | ☐ Grape | ☐ Hazelnut | ☐ Kiwi |
| ☐ Melon | ☐ Nectarine | ☐ Papaya | ☐ Passion Fruit |
| ☐ Peach | ☐ Pear | ☐ Plum | ☐ Pineapple |
| ☐ Raw Potatoes | ☐ Tomatoes | | |

27. After exposure to latex gloves/items, have you experienced any of the following:

| | | | |
|---|---|---|---|
| Wheezing | ☐Yes ☐No | Difficulty breathing | ☐Yes ☐No |
| Sneezing | ☐Yes ☐No | Swelling of eyelids | ☐Yes ☐No |
| Tearing eyes | ☐Yes ☐No | Swelling of lips | ☐Yes ☐No |
| Itchy eyes | ☐Yes ☐No | Abdominal cramps | ☐Yes ☐No |
| Runny nose | ☐Yes ☐No | Hives | ☐Yes ☐No |
| Nausea | ☐Yes ☐No | Rapid heart rate | ☐Yes ☐No |

Other: _____

28. How long have you worked here in a position requiring the use of gloves? _____

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# Appendix 6: Personnel Medical Evaluation Form



29. Did you wear gloves at work prior to your current job? ☐Yes ☐No

30. Did you have any problems then? ☐Yes ☐No

31 Do you currently wear/use latex gloves/items either at home or at another place of employment? ☐Yes ☐No

32. How many months or years would you estimate you have been wearing gloves at work?

☐ < 1 yr ☐ 1-5 yrs ☐ 6-10 yrs ☐ >10 yrs

# Appendix 7: IACUC/OB Membership Roster

Please provide a Committee roster, indicating names, degrees, membership role, and affiliation (e.g., Department/Division).

## *(IACUC)*

**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE**

As of 3/20/18

***Voting Members = 8*** **Quorum = 5**

1. (b)(6)

2 (b)(6)

3. (b)(6)

## Appendix 7: IACUC/OB Membership Roster

4. (b)(6)

5. (b)(6)

6. (b)(6)

7. (b)(6)

8. (b)(6)

# Appendix 7: IACUC/OB Membership Roster

***EX OFFICIO/NON-VOTING MEMBERS***

9. (b)(6)

# Appendix 8: IACUC/OB Minutes

Please provide the latest two Minutes of the IACUC/OB meetings.

**VA MEDICAL CENTER**
**Research Service** (b)(6)
**500 W. Fort Street**
**Boise, ID 83702-4598**

**ANIMAL STUDIES SUBCOMMITTEE MEETING**
**Monday, February 26, 2018,** (b)(6)

VOTING MEMBERS PRESENT:
(b)(6)

VOTING MEMBERS EXCUSED ABSCENCE:
(b)(6)

GUEST PESENT:
(b)(6)

GUEST VIA TELECOMFERENCE:
(b)(6)

Conflict of Interest Statement: Subcommittee members with a real or potential conflict of interest (personally involved or have a financial or institutional conflict) on any voting item are identified in the appropriate section below and were not present during deliberations or voting.

Having determined that a quorum was present (Quorum = 4; 6 of 7 voting members present), the Chair called the meeting to order at 12:30pm.

1. MINUTES

   a. The Committee reviewed the final, unredacted minutes of the IACUC meeting held January 22, 2018. After review, a motion was made and seconded to approve the minutes. The vote was unanimous with 6 for, 0 against, and 0 abstain.

2. OLD BUSINESS

   a. The following VMU work orders have been completed or are in the process of being completed:

      i. None

   b. VMU Work Orders still open

      i. Chain for alcove- no anticipated date.
      ii. Leak in Break room ceiling is in the process of being repaired by FMS, Facility Maintenance Systems.

3. NEW BUSINESS

# Appendix 8: IACUC/OB Minutes

a. Protocol Modification:
   i. (b)(6)

b. Initial Protocol Review:
   (b)(6)

c. Veterinary Report – (b)(6) no animals in the facility.

d. Quality Assurance- Deferred (b)(6) is absent.

e. VMU Manager Report- No information to share.

f. Quality Assurance Items- Deferred

g. Training Exercise #4:

   i. Committee discussed training exercise #4, a sample annual VMU animal report for review by committee members. The exercise asks members to become familiar with the mathematical process of calculating average daily census for the VMU. The exercise presented two species and their populations over a year period for evaluation and discussion by the IACUC members.

h. Informational Items:

   a. Per Diem:
   (b)(6) informed the committee that the idea of charging investigators utilizing space and equipment in the VMU has been tabled for now per request of a handful of investigators within the Research Department. These investigators do not want per diems increased or a fee schedule established for charging investigators using the VMU. It is believed that (b)(6) of the Boise, ID VAMC, will continue to pay the differences in the VMU budget through VERA funds distributed to the Boise VA station from Central Office. This issue will continue to be deliberated with Research and VA leadership.

4. The Subcommittee meeting adjourned at 1:30 pm. The next meeting is scheduled for Monday, March 26, 2018 and will be held if there is business to attend to.

(b)(6)

03/26/2018
Date:

# Appendix 8: IACUC/OB Minutes

**VA MEDICAL CENTER**
**Research Service** (b)(6)
**500 W. Fort Street**
**Boise, ID 83702-4598**

**ANIMAL STUDIES SUBCOMMITTEE MEETING**
**Monday, March 26, 2018, Research** (b)(6)

VOTING MEMBERS PRESENT:
(b)(6)

VOTING MEMBERS EXCUSED ABSCENCE:
(b)(6)

NONVOTING MEMBERS PRESENT:
(b)(6)

GUEST PESENT:
(b)(6)

Conflict of Interest Statement: Subcommittee members with a real or potential conflict of interest (personally involved or have a financial or institutional conflict) on any voting item are identified in the appropriate section below and were not present during deliberations or voting.

Having determined that a quorum was present (Quorum = 4; 6 of 7 voting members present), the Chair called the meeting to order at 12:30pm.

1. MINUTES

a. The Committee reviewed the final, unredacted minutes of the IACUC meeting held February 26, 2018. After review, a motion was made and seconded to approve the minutes. The vote was unanimous with 6 for, 0 against, and 0 abstain.

2. OLD BUSINESS

a. The following VMU work orders have been completed or are in the process of being completed:

i. None

b. VMU Work Orders still open

i. Chain for alcove- no anticipated date.
ii. Leak in Break room ceiling is in the process of being repaired by FMS, Facility Maintenance Systems.

3. NEW BUSINESS

a. Veterinary Report – (b)(6) mentioned that there were mice currently in the VMU facility as part of (b)(6) also mentioned that he had trained multiple individuals over the last month, including new technicians and post-docs, as well as (b)(6) (b)(6)

b. Quality Assurance- Deferred (b)(6) is absent.

c. VMU Manager Report-

i. 102 Animals in the facility.
ii. 2018 second quarter billing is completed.
iii. AAALAC application for accreditations is in the final process and (b)(6) is reviewing the document for finishing touches. The on-sight inspection is anticipated to take place sometime between June and August of this summer.

d. Quality Assurance Items- (b)(6) - The annual report is being worked on and will be presented to the committee in the April meeting.

e. Informational Items:

i. Member ship renewal for:

a. (b)(6) After a brief discussion (b)(6) excused himself from the room, a motion was made and seconded to approve the membership renewal for (b)(6) as IACUC Community voting member. The vote was unanimous with 6 for, 0 against, and 0 abstain.

b. (b)(6) After a brief discussion (b)(6) excused herself from the room, a motion was made and seconded to approve the membership renewal for (b)(6) as IACUC VMU Manager voting member. The vote was unanimous with 6 for, 0 against, and 0 abstain.

c. (b)(6) Chair After a brief discussion (b)(6) excused himself from the room, a motion was made and seconded to approve the IACUC Chair position renewal for (b)(6) as Chair voting member. The vote was unanimous with 6 for, 0 against, and 0 abstain.

ii. (b)(6), a candidate to replace (b)(6) as the alternate community-member for (b)(6), was introduced to the committee by (b)(6) detailed her job and work experience, answered several questions posed by the committee. She expressed a sincere interest in serving on the Boise, ID VA IACUC and was then excused from the room while the committee discussed her qualifications. A motion was made and seconded to approve her membership as an alternate committee member. The vote was unanimous with 6 for, 0 against, and 0 abstain.

4. The Subcommittee meeting adjourned at 1:30 pm. The next meeting is scheduled for Monday, April 23, 2018 and will be held if there is business to attend to.

(b)(6)

03/27/2018
Date:

# Appendix 9: IACUC/OB Protocol Form

Please attach a ***blank*** copy of form(s) used by the IACUC/OB to review and approve studies. Include forms used for annual (or other periodic) renewal, modifications, amendments, etc., as applicable.

**ANIMAL COMPONENT OF RESEARCH PROTOCOL (ACORP)**
**Main Body**
**VERSION 4**

See Instructions for Completion of the Animal Component of Research Protocol (ACORP Instructions), for help in completing specific items.

A. **ACORP Status.**

1. Full Name of Principal Investigator(s)►

2. VA Station Name (City) and 3-Digit Station Number►

3. Protocol Title►

4. Animal Species covered by this ACORP►

5. Funding Source(s). Check each source that applies:

►( ) Department of Veterans Affairs.
►( ) US Public Health Service (e.g. NIH).
►( ) Private or Charitable Foundation -- Identify the Foundation:
►( ) University Intramural Funds – Identify the University and Funding Component:
►( ) Private Company – Identify the Company:
►( ) Other – Identify Other Source(s):

6. Related Documentation for IACUC reference.

   a. If this protocol applies to a project that has already been submitted to the R&D Committee for review, identify the project:

      (1) Title of project►

(2) If approved by the R&D Committee, give the date of approval►

b. Triennial review. If this protocol is being submitted for triennial *de novo* review, complete the following:

(1) Identify the studies described in the previously approved ACORP that have already been completed
►

(2) Indicate the numbers of animals of each breed/strain/genotype that have already been used, and adjust the numbers shown in Item I accordingly
►

(3) Describe any study results that have prompted changes to the protocol, and briefly summarize those changes, to guide the reviewers to the details documented in other Items below.
►

c. List any other relevant previously approved animal use protocols (copy the lines below as needed for each protocol listed).

(1) Title of other protocol ►
(2) IACUC approval number of other protocol ►
Give the name of the VA station or other institution that approved it, if it was not approved by the IACUC that will review this ACORP ►

7. Indicate the type(s) of animal use covered by this protocol (check all that apply):

►( ) Research
►( ) Teaching or Training
►( ) Testing
►( ) Breeding and colony management only; not for any specific research project
►( ) Holding protocol (as specified by local requirements; not required by VA, PHS, or USDA)
►( ) Other. Please specify►

**Proposal Overview**

B. **Description of Relevance and Harm/Benefit Analysis.** Using non-technical (lay) language that a senior high school student would understand, briefly describe how this research project is intended to improve the health of people and/or other animals, or otherwise to serve the good of society, and explain how these benefits outweigh the pain or distress that may be caused in the animals that are to be used for this protocol.
►

# Appendix 9: IACUC/OB Protocol Form

C. **Experimental Design.**

1. **Lay Summary.** Using non-technical (lay) language that a senior high school student would understand, summarize the conceptual design of the experiment in no more than one or two paragraphs.
▶

2. **Complete description of the proposed use of animals.** Use the following outline to detail the proposed use of animals.

a. **Summarize** the design of the experiment in terms of the specific groups of animals to be studied.
▶

b. **Justify the group sizes and the total numbers of animals requested.** A power analysis is strongly encouraged; see ACORP instructions.
▶

c. **Describe each procedure** to be performed on any animal on this protocol. (Use Appendix 9 to document any of these procedures that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
▶

D. **Species.** Justify the choice of species for this protocol.
▶

**Personnel**

E. **Current qualifications and training.** (For personnel who require further training, plans for additional training will be requested in Item F.)

1. PI

Name▶
Animal research experience ▶

Qualifications to perform specific procedures

| Specific procedure(s) that the PI will perform personally | Experience with each procedure in the species described in this ACORP |
|---|---|

| | |
|---|---|
| | |
| | |

2. Other research personnel (copy the lines below for each individual)

Name►
Animal research experience ►

Qualifications to perform specific procedures

| Specific procedure(s) that this individual will perform | Experience with each procedure in the species described in this ACORP |
|---|---|
| | |
| | |

3. VMU animal care and veterinary support staff personnel (copy the lines below for each individual)

Name►

Qualifications to perform specific support procedures in the animals on this protocol

| Specific support procedure(s) assigned to this individual | Qualifications for performing each support procedure in the species described in this ACORP (e.g., AALAS certification, experience, or completion of special training) |
|---|---|
| | |
| | |

4. For each of the research personnel listed in items 1 and 2 above, enter the most recent completion date for each course

| Name of Individual | Working with the VA IACUC | ORD web-based species specific course (Identify the species) | Any other training required locally (Identify the training) |
|---|---|---|---|
| | | | |
| | | | |

F. **Training to be provided.** List here each procedure in Item E for which anyone is shown as "to be trained", and describe the training. For each procedure, describe the type of training to be provided, and give the name(s), qualifications, and training experience of the person(s) who will provide it. If no further training is required for anyone listed in Item E, enter "N/A"

# Appendix 9: IACUC/OB Protocol Form

►

G. **Occupational Health and Safety.**

1. Complete one line in the table below for each of the personnel identified in Item E:

| Name | Enrollment in OHSP | | Declined optional services | Current on Interactions with OHSP? (yes/no) |
|---|---|---|---|---|
| | VA program | Equivalent Alternate Program – identify the program | | |
| | ( ) | ( ) | ( ) | |
| | ( ) | ( ) | ( ) | |
| | ( ) | ( ) | ( ) | |

2. Are there any non-routine OHSP measures that would potentially benefit, or are otherwise required for, personnel participating in or supporting this protocol?

► ( ) Yes. Describe them ►

► ( ) No.

**Animals Requested**

H. **Animals to be Used.** Complete the following table, listing the animals on separate lines according to any specific features that are required for the study (see ACORP Instructions, for guidance, including specific terminology recommended for the "Health Status" column):

| Description (include the species and any other special features not shown elsewhere in this table) | Gender | Age/Size on Receipt | Source (e.g., Name of Vendor, Collaborator, or PI of local breeding colony) | Health Status |
|---|---|---|---|---|
| | | | | |
| | | | | |

# Appendix 9: IACUC/OB Protocol Form

I. **Numbers of animals requested.** See ACORP Instructions, for descriptions of the categories and how to itemize the groups of animals.

**USDA Category B**

| Procedures▶ | | | | | | |
|---|---|---|---|---|---|---|
| Species / Experimental Group / Procedures(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | **Category B TOTAL** |
| | | | | | | |
| | | | | | | |

**USDA Category C**

| Procedures▶ | | | | | | |
|---|---|---|---|---|---|---|
| Species / Experimental Group / Procedure(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | **Category C TOTAL** |
| | | | | | | |
| | | | | | | |

**USDA Category D**

| Procedures▶ | | | | | | |
|---|---|---|---|---|---|---|
| Species / Experimental Group / Procedure(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | **Category D TOTAL** |
| | | | | | | |
| | | | | | | |

**USDA Category E**

| Procedures▶ | | | | | | |
|---|---|---|---|---|---|---|
| Species / Experimental Group / Procedure(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | **Category E TOTAL** |
| | | | | | | |
| | | | | | | |

**TOTALS over all Categories**

# Appendix 9: IACUC/OB Protocol Form

| Species / Experimental Group /Procedure(s) | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | **GRAND TOTAL** |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |

J. **Management of USDA Category D procedures.** Indicate which statement below applies, and provide the information requested.

► ( ) This protocol does NOT include any Category D procedures.

► ( ) This protocol INCLUDES Category D procedures. List each Category D procedure and provide the information requested. (For surgical procedures described in Appendix 5, only identify the procedure(s) and enter "See Appendix 5 for details.)

| Procedure | Monitoring (indicate the method(s) to be used, and the frequency and duration of monitoring through post-procedure recovery) | Person(s) responsible for the monitoring | Method(s) by which pain or distress will be alleviated during or after the procedure (include the dose, route, and duration of effect of any agents to be administered) |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

K. **Justification of Category E procedures.** Indicate which statement below applies, and provide the information requested.

► ( ) This protocol does NOT include any Category E procedures

► ( ) This protocol INCLUDES Category E procedures. Identify each Category E procedure included in this ACORP and justify scientifically why the pain or distress cannot be relieved.

►

## Veterinary Care and Husbandry

L. **Veterinary Support.**

1. Identify the laboratory animal veterinarian who is responsible for ensuring that the animals on this protocol receive appropriate veterinary medical care.

# Appendix 9: IACUC/OB Protocol Form

Name►
Institutional affiliation►
email contact►

2. Veterinary consultation during the planning of this protocol.

   Name of the laboratory animal veterinarian consulted►
   Date of the veterinary consultation (meeting date, or date of written comments provided by the veterinarian to the PI) ►

M. **Husbandry.** As a reference <u>for the animal husbandry staff</u>, summarize here the husbandry requirements of the animals on this protocol. (Use Appendix 6 to justify the use of any special husbandry and to detail its effects on the animals. Use Appendix 9 to document any aspects of the husbandry that involve "departures" from the standards in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

1. Caging needs. Complete the table below to describe the housing that will have to be accommodated by the housing sites for this protocol:

| a. Species | b. Type of housing* | c. Number of individuals per housing unit** | d. Is this housing consistent with the *Guide* and USDA regulations? (yes/no***) | e. Estimated maximum number of housing units needed at any one time |
|---|---|---|---|---|
| | | | | |
| | | | | |

*See ACORP Instructions, for guidance on describing the type of housing needed. If animals are to be housed according to a local Standard Operating Procedure (SOP), enter "standard (see SOP)" here, and enter the SOP into the table in Item Y. If the local standard housing is not described in a SOP, enter "standard, see below" in the table and describe the standard housing here:
►

** The *Guide* states that social animals should generally be housed in stable pairs or groups. Provide a justification if any animals will be housed singly (if species is not considered "social", then so note)
►

***Use Appendix 9 to document "departures" from the standards in the *Guide*.

2. Enrichment. Complete the table below to indicate whether "standard" exercise and environmental enrichment will be provided to the animals on this protocol, or whether any special supplements or restrictions will be required (See ACORP Instructions, for more

information on enrichment requirements. Use Appendix 9 to document any enrichments requirements that represent "departures" from the standards in the *Guide*.):

| a. Species | b. Description of Enrichment* | c. Frequency |
|---|---|---|
| | | |
| | | |

*If enrichment will be provided according to a local SOP, enter "standard (see SOP)" and enter the SOP into the table in Item Y. If the local standard enrichment is not described in a SOP, enter "standard, see below", and describe the standard species-specific enrichment here.
►

3. Customized routine husbandry. Check all of the statements below that apply to the animals on this protocol, and provide instructions to the animal husbandry staff with regard to any customized routine husbandry needed.

► ( ) This ACORP INCLUDES genetically modified animals.

List each group of genetically modified animals, and describe for each any expected characteristic clinical signs or abnormal behavior related to the genotype and any customized routine husbandry required to address these. For genetic modifications that will be newly generated on or for this protocol, describe any special attention needed during routine husbandry to monitor for unexpected clinical signs or abnormal behavior that may require customized routine husbandry.
►

► ( ) Devices that extend chronically through the skin WILL be implanted into some or all animals on this protocol. Describe any customized routine husbandry to be provided by animal husbandry staff to minimize the chances of chronic infection where the device(s) penetrate the skin.
►

► ( ) Some or all of the animals on this protocol WILL require other customized routine husbandry by the animal husbandry staff, beyond what has been described above. Describe the special husbandry needed.
►

► ( ) This ACORP does NOT include use of any animals that will require customized routine husbandry.

N. **Housing Sites**. Document in the tables below each location where animals on this protocol may be housed.

► ( ) Housing on VA property. Identify each location on VA property where animals on this protocol will be housed, and indicate whether or not each location is inside the VMU.

# Appendix 9: IACUC/OB Protocol Form

| Building | Room number | Inside of VMU? | |
|---|---|---|---|
| | | Yes | No |
| | | ( ) | ( ) |
| | | ( ) | ( ) |
| | | ( ) | ( ) |

► ( ) Housing in non-VA facilities. Identify each location not on VA property where animals on this protocol will be housed, and provide the information requested in the table.

| Name of Non-VA Facility | Is this facility accredited by AAALAC? | | Building | Room Number |
|---|---|---|---|---|
| | Yes -- enter status* | No** | | |
| | ( ) | ( )** | | |
| | ( ) | ( )** | | |
| | ( ) | ( )** | | |

*See ACORP Instructions, for a list of AAALAC accreditation status options.

**For any facility listed above that is not accredited by AAALAC, attach documentation that a waiver has been granted by the CRADO.

## Special Features

O. **Antibody Production.** Will any of animals on this protocol be used for the production of antibodies?

► ( ) Some or all of the animals on this protocol WILL be used in the production and harvesting of antibodies. Check "Appendix 2" in Item Y, below, and complete and attach Appendix 2, "Antibody Production".

► ( ) NO animals on this protocol will be used in the production and harvesting of antibodies.

P. **Biosafety.** Will any substances (other than those used in routine husbandry or veterinary care) be administered to the animals on this protocol?

► ( ) This protocol INVOLVES administration of substances to the animals other than those used in routine husbandry and veterinary care. Check "Appendix 3" in Item Y, below, and complete and attach Appendix 3, "Biosafety".

# Appendix 9: IACUC/OB Protocol Form

► ( ) This protocol does NOT involve administration of any substances to the animals other than those used in routine husbandry and veterinary care.

Q. **Locations of procedures.** Complete the table below, listing the location(s), inside or outside of the animal facility, for each of the procedures to be performed on animals on this protocol.

| Procedure | Surgical? | | Bldg/Room Number | Requires transport through non-research areas? | |
|---|---|---|---|---|---|
| | Yes | No | | Yes – describe method of discreet transport | No |
| | ( ) | ( ) | | ( ) | ( ) |
| | ( ) | ( ) | | ( ) | ( ) |
| | ( ) | ( ) | | ( ) | ( ) |
| | ( ) | ( ) | | ( ) | ( ) |

R. **Body Fluid, Tissue, and Device Collection.** List each body fluid, tissue, or device to be collected, and complete the table below to indicate the nature of the collection. Check the relevant Appendices in Item Y, below, and complete and attach them, as shown in the column headings.

| Body Fluid, Tissue, or Device to be Collected | Collected AFTER Euthanasia | Collected BEFORE Euthanasia | | |
|---|---|---|---|---|
| | | Blood Collection Associated with Antibody Production (Appendix 2, "Antibody Production") | Collected as Part of a Surgical Procedure (Appendix 5, "Surgery") | Other Collection from Live Animals (Appendix 4, "Antemortem Specimen Collection") |
| | ( ) | ( ) | ( ) | ( ) |
| | ( ) | ( ) | ( ) | ( ) |
| | ( ) | ( ) | ( ) | ( ) |

S. **Surgery.** Does this protocol include any surgical procedure(s)?

► ( ) Surgery WILL BE PERFORMED on some or all animals on this protocol. Check "Appendix 5" in Item Y, below, and complete and attach Appendix 5, "Surgery".

# Appendix 9: IACUC/OB Protocol Form

► ( ) NO animals on this protocol will undergo surgery.

T. **Endpoint criteria.** Describe the criteria that will be used to determine when animals will be removed from the protocol or euthanatized to prevent suffering. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these criteria. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
►

U. **Termination or removal from the protocol.** Complete each of the following that applies:

► ( ) Some or all animals will NOT be euthanatized on this protocol. Describe the disposition of these animals. (Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these methods of disposition. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)
►

► ( ) Some or all animals MAY be euthanatized as part of the planned studies. Complete the table below to describe the exact method(s) of euthanasia to be used. (Use Appendix 9 to document any departures from the standards in the *Guide* represented by these methods. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

| Check each method that may be used on this protocol | Method of Euthanasia | Species | AVMA Classification | | |
|---|---|---|---|---|---|
| | | | Acceptable | Conditionally Acceptable | Unacceptable |
| ( ) | $CO_2$ from a compressed gas tank<br>Duration of exposure after apparent clinical death►<br>Method for verifying death►<br>Secondary physical method► | | ( ) | ( ) | ( ) |

# Appendix 9: IACUC/OB Protocol Form

| | | | | | |
|---|---|---|---|---|---|
| ( ) | Anesthetic overdose<br>Agent▶<br>Dose▶<br>Route of administration▶ | | ( ) | ( ) | ( ) |
| ( ) | Decapitation under anesthesia<br>Agent▶<br>Dose▶<br>Route of administration▶ | | ( ) | ( ) | ( ) |
| ( ) | Exsanguination under anesthesia<br>Agent▶<br>Dose▶<br>Route of administration▶ | | ( ) | ( ) | ( ) |
| ( ) | Other (Describe) ▶ | | ( ) | ( ) | ( ) |
| ( ) | Other (Describe) ▶ | | ( ) | ( ) | ( ) |

1. For each of the methods above that is designated as "Conditionally Acceptable" by the AVMA, describe how the conditions for acceptability will be met:
   ▶

2. For each of the methods above that is designated as "Unacceptable" by the AVMA, give the scientific reason(s) that justify this

deviation from the AVMA Guidelines:
►

3. Identify all research personnel who will perform euthanasia on animals on this protocol and describe their training and experience with the methods of euthanasia they are to use in the species indicated.
►

4. Instructions for the animal care staff in case an animal is found dead.
   a. Describe the disposition of the carcass, including any special safety instructions. If disposition is to be handled according to a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.
   ►

   b. Describe how the PI's staff should be contacted.
   ► ( ) Please contact a member of the PI's staff immediately. (Copy the lines below for each individual who may be contacted)
   Name►
   Contact Information►

   ► ( ) There is no need to contact the PI's staff immediately. Describe the routine notification procedures that will be followed. If the routine notification procedures are described in a local SOP, enter "according to local SOP" and enter the information requested about the SOP into the table in Item Y.
   ►

V. **Special Procedures.** List each special procedure (including special husbandry and other special procedures) that is a part of this protocol, and specify where the details of the procedure are documented. See ACORP Instructions, for examples.

| Name of Procedure | Identify Where the Details of the Procedure are Documented | | |
|---|---|---|---|
| | SOP (title or ID number)* | Other Items in this ACORP -- specify the Item letter(s) | Appendix 6 |
| | | Items: | ( )** |
| | | Items: | ( )** |
| | | Items: | ( )** |

# Appendix 9: IACUC/OB Protocol Form

| | | Items: | ( )** |
|---|---|---|---|

*If any special procedure is detailed in a SOP, identify the SOP and enter the information requested about the SOP in the table in Item Y.

**If any special procedure is detailed in Appendix 6, check "Appendix 6" in Item Y, below, and complete and attach Appendix 6.

(Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

W. **Consideration of Alternatives and Prevention of Unnecessary Duplication.** These are important to minimizing the harm/benefit to be derived from the work.

1. Document the database searches conducted.
   List each of the potentially painful or distressing procedures included in this protocol.

   Then complete the table below to document how the database search(es) you conduct to answer Items W.2 through W.5 below address(es) each of the potentially painful or distressing procedures.

| Name of the database | Date of search | Period of years covered by the search | Potentially painful or distressing procedures addressed | Key words and/or search strategy used | Indicate which mandate each search addressed | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Replacement of animals (item W.2) | Reduction in numbers of animals used (item W.3) | Refinement to minimize pain or distress (item W.4) | Lack of unnecessary duplication (item W.5) |
| | | | | | ( ) | ( ) | ( ) | ( ) |
| | | | | | ( ) | ( ) | ( ) | ( ) |
| | | | | | ( ) | ( ) | ( ) | ( ) |
| | | | | | ( ) | ( ) | ( ) | ( ) |

2. Replacement. Describe the replacements that have been incorporated into this work, the replacements that have been considered but cannot be used, and the reason(s) that further replacements are not acceptable.
▶

3. Reduction. Describe how the number of animals to be used has been minimized in this protocol and explain why further reduction would disproportionately compromise the value of the data.
▶

4. Refinement. Describe the refinements that have been incorporated into this work and explain why no further refinements are feasible.
▶

5. Describe how it was determined that the proposed work does not unnecessarily duplicate work already documented in the literature.
▶

X. **Other Regulatory Considerations.**

1. **Controlled drugs.**

a. Complete the table below for each drug that is used in animals on this protocol and that is classified as a controlled substance by the DEA. See ACORP Instructions, for explanations about the information requested.

| Controlled substances | Storage | | Personnel Authorized to Access | Location for Use | | Procurement | |
|---|---|---|---|---|---|---|---|
| | Double-locked | Not Double-locked* | | VA Property | Not on VA Property | VA Phar-macy | Non-VA |
| | ( ) | ( )* | | ( ) | ( ) | ( ) | ( ) |
| | ( ) | ( )* | | ( ) | ( ) | ( ) | ( ) |
| | ( ) | ( )* | | ( ) | ( ) | ( ) | ( ) |

*For any controlled substance that will NOT be stored under double lock, with limited access, describe how it will be stored, and explain why this is necessary.
▶

b. Check each statement below that applies, to confirm that all controlled substances used on this protocol will be procured according to VA pharmacy policies:

► ( ) Some controlled substances will used on VA property, and all of these will be obtained through the local VA pharmacy.

► ( ) Some controlled substances will not be obtained through the local VA pharmacy, but none of these will be used on VA property. See the ACORP Instructions, for further information.

► ( ) Other. Explain►

2. **Human patient care equipment or procedural areas.** Does this protocol involve use of any human patient care equipment or procedural areas?

► ( ) Yes, some human patient care equipment or procedural area(s) will be used for the animal studies on this protocol. Check "Appendix 7" in Item Y, below, and complete and attach Appendix 7, "Use of Patient Procedural Areas for Animal Studies".

► ( ) No human patient care equipment or procedural areas will be used for the animal studies on this protocol.

3. **Explosive agents.** Does this protocol involve use of any explosive agent?

► ( ) Yes, some explosive agent(s) will be used on this protocol. Check "Appendix 3" and "Appendix 8" in Item Y, below, and complete and attach Appendix 8, "Use of Explosive Agent(s) within the Animal Facility or in Animals", as well as Appendix 3, "Biosafety".

► ( ) No explosive agent(s) will be used as part of this protocol.

Y. **Summary of Attachments.** To assist the reviewers, summarize here which of the following apply to this ACORP.

**Appendices.** Indicate which of the Appendices are required and have been completed and attached to this protocol. Do not check off or attach any appendices that are not applicable to this ACORP.

► ( ) Appendix 1, "Additional Local Information"
► ( ) Appendix 2, "Antibody Production"
► ( ) Appendix 3, "Biosafety"
► ( ) Appendix 4, "Ante-mortem Specimen Collection"
► ( ) Appendix 5, "Surgery"
► ( ) Appendix 6, "Special Husbandry and Procedures"
► ( ) Appendix 7, "Use of Patient Care Equipment or Areas for Animal Studies"
► ( ) Appendix 8, "Use of Explosive Agent(s) within the VMU or in Animals"
► ( ) Appendix 9, "Departures from "Must" and "Should" Standards in the *Guide*"

# Appendix 9: IACUC/OB Protocol Form

**Standard Operating Procedures (SOPs).** List in the table below, each of the SOPs referred to in this protocol, providing the information requested for each one. The approved SOPs must be included when the approved ACORP and Appendices are submitted for Just-in-Time processing before release of VA funding support.

| Item | SOP | | Approval Date |
|---|---|---|---|
| | Title | ID | |
| C.2.c | | | |
| M.1 | | | |
| M.2 | | | |
| U.4.a | | | |
| U.4.b | | | |
| V | | | |
| | | | |
| | | | |

Z. **Certifications.** Signatures are required here for any ACORP that is to be submitted to VA Central Office in support of an application for VA funding. Include the typed names and dated signatures as shown below for the Main Body of the ACORP and for each of the Appendices that apply to this protocol. Do NOT include signatures for, or attach, any appendices that do NOT apply.

1. **Main Body of the ACORP.**

   a. **Certification by Principal Investigator(s):**

   I certify that, to the best of my knowledge, the information provided in this ACORP is complete and accurate, and the work will be performed as described here and approved by the IACUC. I understand that IACUC approval must be renewed at least annually, and that the IACUC must perform a complete *de novo* review of the protocol at least every three years, if work is to continue without interruption. I understand further that I am responsible for providing the information required by the IACUC for these annual and triennial reviews, allowing sufficient time for the IACUC to perform the reviews before the renewal dates, and that I may be required to complete a newer version of the ACORP that requests additional information, at the time of each triennial review.

   I understand that further IACUC approval must be secured before any of the following may be implemented:

   - Use of additional animal species, numbers of animals, or numbers of procedures performed on individual animals;
   - Changing any procedure in any way that has the potential to increase the pain/distress category to which the animals should

be assigned, or that might otherwise be considered a significant change from the approved protocol;
- Performing any additional procedures not already described in this ACORP;
- Use of any of these animals on other protocols, or by other investigators.

I further certify that:

- No personnel will perform any animal procedures on this protocol until the IACUC has confirmed that they are adequately trained and qualified, enrolled in an acceptable Occupational Health and Safety Program, and meet all other criteria required by the IACUC. When new or additional personnel are to work with the animals on this protocol, I will provide this information to the IACUC for confirmation before they begin work;
- I will provide my after-hours contact information to the animal care staff for use in case of emergency.

| Name(s) of Principal Investigator(s) | Signature | Date |
|---|---|---|
| | | |
| | | |

b. **Certification by IACUC Officials.**

We certify that:

- We, with the IACUC, have evaluated the care and use of animals described on this ACORP, in accordance with the provisions of the USDA Animal Welfare Act Regulations and Standards, PHS Policy, the *Guide for the Care and Use of Laboratory Animals*, and VA Policy;
- The IACUC has determined that the care and use of animals described in this ACORP is appropriate, and has therefore approved the protocol;
- The full text of any minority opinions is documented here as indicated below:

► ( ) No minority opinions were submitted by any IACUC participant for inclusion.

► ( ) Minority opinions submitted by IACUC participants are copied here
►

► ( ) Minority opinions submitted by IACUC participants are attached on separate pages labeled "IACUC Minority Opinion" (indicate the number of pages► )

| Name of Attending Veterinarian (VMO or VMC) | Signature | Date |
|---|---|---|
| | | |
| Name of IACUC Chair | Signature | Date |
| | | |

2. **Appendix 2. Antibody Production.** No signatures required.

3. **Appendix 3. Biosafety.**

   a. **Certification by PI(s) and IACUC Officials:**

   We certify that:

   - Before any animal experiments involving hazardous agents (identified in Item 10.a of Appendix 3) are performed, SOPs designed to protect all research and animal facility staff as well as non-study animals will be developed and approved by the appropriate VA or affiliated university safety committee and by the IACUC;
   - All personnel who might be exposed to the hazardous agents (identified in Item 10.a of Appendix 3) will be informed of possible risks and will be properly trained ahead of time to follow the SOPs to minimize the risks of exposure.

| Name(s) of Principal Investigator(s) | Signature(s) | Date |
|---|---|---|
| | | |
| | | |

# Appendix 9: IACUC/OB Protocol Form

| Name of Institutional Veterinarian | Signature | Date |
|---|---|---|
| | | |
| Name of IACUC Chair | Signature | Date |
| | | |

b. **Certification by Biosafety Official.** I certify that:

- Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "toxic", "infectious", "biological", or "contains recombinant nucleic acid";
- The use of each of the agents thus identified as "toxic", "infectious", or "biological", or "contains recombinant nucleic acid" is further documented as required in Items 4, 5, 6, and/or 8, as applicable, and in Item 10.a of Appendix 3;
- The use of each of these agents has been approved by the appropriate committee(s) or official(s), as shown in Item 10.a of Appendix 3.

| Name of the Biosafety Officer, or of the Chair of the Research Safety or Biosafety Committee | Signature | Date |
|---|---|---|
| | | |
| | | |

c. **Certification by Radiation Safety Official.** I certify that:

- Each agent to be administered to animals on this protocol has been properly identified in Item 1 of Appendix 3 as to whether it is "radioactive";

- The use of each radioactive agent is further documented as required in Items 7 and 10.a of Appendix 3;
- The use of each radioactive agent has been approved by the appropriate committee(s), as shown in Item 10.a of Appendix 3.

| Name of the Radiation Safety Officer, or of the Chair of the Radiation Safety or Isotope Committee | Signature | Date |
|---|---|---|
| | | |
| | | |

4. **Appendix 4. Ante-mortem Specimen Collection.** No signatures required.

5. **Appendix 5. Surgery. Certification by the PI(s).** I certify that:

- To the best of my knowledge, the information provided in Appendix 5 of this ACORP is complete and accurate;
- The surgical procedures will be performed and the post-operative care (including administration of post-operative analgesics) will be provided as described;
- The spaces where any survival surgical procedures will be performed (listed in Item 4 of Appendix 5) are suitable for sterile/aseptic surgery;
- The names and contact information for research personnel to notify or consult in case of emergencies will be provided to the VMU supervisor and veterinary staff;
- Post-operative medical records will be maintained and readily available for the veterinary staff and the IACUC to refer to, and will include the following:

  - Identification of each animal such that care for individual animals can be documented.
  - Daily postoperative medical records for each animal, that include documentation of daily evaluation of overall health and descriptions of any complications noted, treatments provided, and removal of devices such as sutures, staples, or wound clips;
  - Documentation of the administration of all medications and treatments given to the animals, including those given to reduce pain or stress.
  - Daily records covering at least the period defined as "post-operative" by local policy.
  - The signature or initials of the person making each entry.

# Appendix 9: IACUC/OB Protocol Form

| Name(s) of Principal Investigator(s) | Signature(s) | Date |
|---|---|---|
| | | |
| | | |

6. **Appendix 6. Special Husbandry and Procedures.** No signatures required.

7. **Appendix 7. Use of Patient Care Equipment or Areas for Animal Studies.**

   a. **Certification by the Principal Investigator(s).** I certify that, to the best of my knowledge, the information provided in Appendix 7 of this ACORP is complete and accurate, and the use of patient care equipment or areas for these animal studies will be as described.

| Name(s) of Principal Investigator(s) | Signature(s) | Date |
|---|---|---|
| | | |
| | | |

   b. **Certification by the officials responsible for the use of any human patient care equipment in animal procedural areas.** Each of the following must sign to indicate that they have granted approval for the human patient care equipment to be moved to the VMU or other animal procedural area to be used on animals and then returned to the human patient care area, as described in Appendix 7. Leave this section blank, if not applicable.

| Name of IACUC Chair | Signature | Date |
|---|---|---|

| | | |
|---|---|---|
| Name of the Manager of the Human Patient Care Equipment | Signature | Date |
| | | |

c. **Certification by the officials responsible for the use of the equipment in human patient care areas for these animal studies.** Each of the following must sign to indicate that they have granted approval for animals to be transported into human patient care areas for study or treatment, as described in Appendix 7. Leave this section blank, if not applicable.

| Name of IACUC Chair | Signature | Date |
|---|---|---|
| | | |
| Name of Attending Veterinarian (VMO or VMC) | Signature | Date |
| | | |
| Name of the Chair of the Clinical Executive Board, or the Service Chief responsible for the Patient Care Area and Equipment | Signature | Date |
| | | |
| Name of ACOS for R&D | Signature | Date |
| | | |
| Name of Chief of Staff | Signature | Date |

| | | |
|---|---|---|
| Name of Director or CEO of the Facility (Hospital or Clinic) | Signature | Date |
| | | |

8. **Appendix 8. Use of Explosive Agent(s) within the Animal Facility or in Animals.**

   a. **Certification by the Principal Investigator(s).**

   I certify that, to the best of my knowledge, the information provided in Appendix 8 of this Animal Component of Research Protocol (ACORP) is complete and accurate, and the use of explosive agents in these animal studies will be as described.

   I further certify that:

   - Procedures involving explosive agent(s) will be performed within a properly operating, ventilated safety hood;
   - All electrical equipment operating when explosive agent(s) are in use will be positioned and powered outside of the hood;
   - Once the seal is broken on any containers of explosive agents, they will be kept in a safety hood throughout use, stored in an explosion-proof refrigerator or other approved storage area, and discarded properly once completely emptied;
   - Proper procedures will be used for safe and appropriate disposal of items (including animal carcasses) that may contain residual traces of the explosive agent(s).

| Name(s) of Principal Investigator(s) | Signature(s) | Date |
|---|---|---|
| | | |
| | | |

   b. **Certification by the officials responsible for overseeing the use of explosive agent(s) in this protocol.** Each of the following must sign to verify that they or the committee they represent have granted approval.

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| Name of IACUC Chair | Signature | Date |
|---|---|---|
| | | |
| Name of Attending Veterinarian (VMO or VMC) | Signature | Date |
| | | |
| Name of Safety/Biosafety Officer for the Facility | Signature | Date |
| | | |
| Name of ACOS for R&D | Signature | Date |
| | | |
| Name of VISN Regional Safety Officer | Signature | Date |
| | | |

9. **Departures from "Must" and "Should" Standards in the *Guide*.** No signatures required.

# Appendix 9: IACUC/OB Protocol Form

**ACORP Appendix 1**
**ADDITIONAL LOCAL INFORMATION**
**VERSION 4**

(This appendix may be used to collect additional information required by the local IACUC. See ACORP App. 1 Instructions, for more detailed explanations of the information requested.)

# Appendix 9: IACUC/OB Protocol Form

**ACORP APPENDIX 2**
**ANTIBODY PRODUCTION**
**VERSION 4**

See ACORP App. 2 Instructions, for more detailed explanations of the information requested.

1. **Immunization.** Provide the information requested below for any animals to be used for raising antibodies specifically for use in this protocol.

   a. Describe the immunization protocol in the table below, using a separate row for each day on which any agent (including primer, antigen, and/or adjuvant) will be administered. (Make sure that each primer, antigen, and adjuvant is also included in Appendix 3.)

| Immunization day (e.g. day -7, 0, 7, 30, etc.) | Antigen | | Adjuvant – give name, concentration, and volume (ml) | Total injection volume (ml) per animal (antigen plus adjuvant) | Divided among how many injection sites? | Injection route and location of injection site(s) on body |
|---|---|---|---|---|---|---|
| | Name | Total amount (mg) and volume (ml) | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

   b. Describe how each antigen will be screened to make sure that it does not harbor infectious agents that could infect other laboratory animals or people after injection.
   ▶

   c. List possible adverse effects that might be observed in animals receiving the proposed primer, antigen, and/or adjuvant injections, and describe the measures that will be taken if these adverse effects occur:
   ▶

d. Give the justification for using any primer or adjuvant that is expected to cause pain or distress in the animals.
►

2. **Survival Blood Collection.** Will blood be collected as a survival procedure for the production and harvesting of antibodies on this protocol?

► ( ) No, the production and harvest of antibodies on this protocol does not involve survival collection of blood.

► ( ) Yes, this protocol requires the collection of blood in a survival procedure, before (as a "pre-bleed") and/or after immunization. Make sure this is included in Item R of the ACORP, and complete items 2.a, 2.b, and 2.c, below.

a. Describe each survival collection of blood in the table below, including any "pre-bleeds" prior to immunizations:

| Site of Blood Collection | Amount of Blood Collected at any one time, expressed as volume (ml) and as % of body weight (assume 1 ml = 1 gram) | Number of Blood Collections | Time Interval(s) Between Successive Collections | Volume Replace-ment? (yes/no) |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |

b. Will anesthetics, tranquilizers, or analgesics be administered for blood collection?

► ( ) No anesthetics, tranquilizers, or analgesics will be administered for blood collection. Explain why it is appropriate or necessary NOT to administer pain-relieving agents:
►

► ( ) Yes. Describe the administration of pain-relieving agents, including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):
►

c. Will volume replacement be provided for blood that is collected?

► ( ) Volume will NOT be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume will NOT be replaced, explain why not.
►

► ( ) Volume WILL be replaced for some of the blood collection listed. For each collection listed in Item 2.a, above, for which volume WILL be replaced, describe the replacement(s) that will be provided (including the composition of the replacement(s), volume, and route of administration).
►

3. **Terminal Blood Collection.** Will animals be euthanatized by exsanguination, for harvest of antibodies?

► ( ) No, this protocol does NOT involve terminal blood collection for harvest of antibodies.
► ( ) Yes, this protocol DOES require terminal blood collection for the harvest of antibodies. Make sure this is included in Item R of the ACORP, and complete Items 3.a., 3. b., and 3.c., below:

a. Describe the method(s) to be used for euthanasia and exsanguination:
►

b. Will anesthetics, tranquilizers, or analgesics be administered for exsanguination?

► ( ) No anesthetics, tranquilizers, or analgesics will be administered for the exsanguination(s). Explain why it is appropriate or necessary NOT to administer pain-relieving agents:

►

► ( ) Yes. Describe the administration of pain-relieving agents including the name of each agent, and its dose (mg/kg), volume (ml), and route and frequency/duration of administration (Make sure this information is also included in Appendix 3):

►

c. Describe how you will make sure that the animals are dead after collection of the blood:
►

4. **Harvesting Feeder Cells.** Describe the exact procedures (including administration of pain-relieving agents) that will be used on any donor animals from which feeder cells will be collected for this protocol, and estimate the number of animals needed for this purpose. Make sure that these animals are included in Item I of the ACORP, and that the harvesting of feeder cells is included in Item R of the ACORP.
►

5. **Expansion of Hybridoma Cell Line(s) *in vivo*.** Will any animals be used to expand hybridoma cell lines so that antibody can be harvested from ascites fluid?

► ( ) No animals will be used on this protocol for *in vivo* expansion of hybridoma cell lines.
► ( ) Yes, this protocol requires use of some animals for *in vivo* expansion of hybridoma cell lines. Make sure that the animals used for this are included in Item I of the ACORP, the priming agent and the hybridoma cells are documented in Appendix 3, and the collection of ascites fluid is included in Item R of the ACORP. Complete items 5.a, 5.b, and 5.c, below.

a. Explain why alternate research methods that do not require the use of additional animals (e.g., *in vitro* cell culture systems for harvesting monoclonal antibodies) are not adequate to meet the research objectives of this project.
►

b. Complete the following table to summarize the procedures to be performed in expanding the hybridoma cell lines and collecting ascites fluid:

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| Hybridoma cell line designation | Number of animals to be used for ascites production | Priming agent and volume | Number and timing of priming injections | Volume of injected hybridoma cells | Number of abdominal taps before euthanasia |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

c. Describe the exact procedures (including administration of pain-relieving agents) that will be used for the abdominal taps to be performed on this protocol

d. List the criteria for euthanasia of animals prior to the last planned abdominal tap.

(Use Appendix 9 to document any "departures" from the standards in the *Guide* represented by these procedures. Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.)

# Appendix 9: IACUC/OB Protocol Form

**ACORP APPENDIX 3**
**BIOSAFETY**
**VERSION 4**

See ACORP App. 3 Instructions, for more detailed explanations of the information requested.

1. **Summary of <u>All</u> Materials Administered to Animals on this Protocol.** Complete the table below for <u>all</u> materials to be administered to any animal on this protocol, indicating the nature of the material by marking EVERY box that applies, and indicating the BSL number for any infectious agents:

| **Material** (Identify the specific agent, device, strain, construct, isotope, etc.) | **Source** (Identify the vendor or colleague, or specify which animals on this protocol will serve as donors) | **Nature of Material** | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | Toxic Agent (Item 4) | Infectious Agent (Item 5) -- Enter the CDC Biosafety Level (BSL 1, 2, 3, or 4) | Biological Agent (Item 6) | Radioactive Agent (Item 7) | Contains Recombinant Nucleic Acid (Item 8) | Routine Pre- or Post-Procedural ☐Drug | Euthanasia agent |
| | | ( ) | ( )BSL_ | ( ) | ( ) | ( ) | ( ) | ( ) |
| | | ( ) | ( )BSL_ | ( ) | ( ) | ( ) | ( ) | ( ) |
| | | ( ) | ( )BSL_ | ( ) | ( ) | ( ) | ( ) | ( ) |
| | | ( ) | ( )BSL_ | ( ) | ( ) | ( ) | ( ) | ( ) |
| | | ( ) | ( )BSL_ | ( ) | ( ) | ( ) | ( ) | ( ) |
| | | ( ) | ( )BSL_ | ( ) | ( ) | ( ) | ( ) | ( ) |

# Appendix 9: IACUC/OB Protocol Form

# Appendix 9: IACUC/OB Protocol Form

2. **Summary of How Materials will be Administered.** Complete the table below for each of the materials shown in the table in Item 1 above:

| **Material*** (Identify the specific agent, device, strain, construct, isotope, etc.) | **Dose** (e.g., mg/kg, CFU, PFU, number of cells, mCi) and **Volume** (ml) | **Diluent* or Vehicle*** | **Route** of admin | **Frequency or duration** of admin | **Reason** for Administration and **Expected Effects** | Location of **Further Details** in this ACORP (specify "Main Body" or "App #", and identify the Item) | Administration Under **Anesthesia, sedation, or tranquilization** (Y/N) |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

*Each material, diluent, or vehicle that is listed as FDA approved or is labeled "USP" is pharmaceutical grade. Check on-line for formulations that are FDA approved for administration to humans (http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm) or animals (http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/UCM042847). Designate with a * each material and each diluent or vehicle to be used that is not pharmaceutical grade. For each of these, explain here why the use of a non-pharmaceutical grade formulation is necessary, and describe how it will be ensured that the material is suitable for use. (See ACORP App. 3 Instructions, for specifics about the level of detail required.)
►

3. **Anesthesia, Sedation, or Tranquilization.** Complete 3.a. and 3.b. below:

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a. For each material with "Y" entered in the last column of the table in Item 2 above, describe the anesthesia, sedation, or tranquilization to be used, identifying the anesthetic, sedative, or chemical tranquilizer, and detailing the dose, volume, and route of administration (Make sure that these agents are also included in Item 1 of this appendix, as materials to be administered):
▶

b. For each material with "N" entered in the last column of the table in Item 2 above, explain why no anesthesia, sedation, or tranquilization is necessary, or can be provided, and describe any alternate methods of restraint that will be used.
▶

4. **Toxic Agents.** Complete the table below for each of the materials listed as a "toxic agent" in the table in Item 1 above, checking the all of the properties that apply (see ACORP App. 3 Instructions, for details).

| Name of Toxic Agent | a. Mutagen | b. Carcinogen | c. Teratogen | d. Select Agent? | | | e. Other – specify toxic properties |
|---|---|---|---|---|---|---|---|
| | | | | Not a Select Agent | Select Agent Used in Sub-threshold Quantities | Select Agent that Requires Registration/Approval | |
| | ( ) | ( ) | ( ) | ( ) | ( ) | ( )* | ( )▶ |
| | ( ) | ( ) | ( ) | ( ) | ( ) | ( )* | ( )▶ |
| | ( ) | ( ) | ( ) | ( ) | ( ) | ( )* | ( )▶ |
| | ( ) | ( ) | ( ) | ( ) | ( ) | ( )* | ( )▶ |
| | ( ) | ( ) | ( ) | ( ) | ( ) | ( )* | ( )▶ |
| | ( ) | ( ) | ( ) | ( ) | ( ) | ( )* | ( )▶ |

*For each "select agent" that requires registration/approval (copy the lines below for each agent):

Name of agent ▶

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Registered with CDC or USDA ►
Registration Number ►
Registration Date ►
Expiration Date of Registration ►

Name of official who granted approval on behalf of VACO►
Date of approval►

5. **Infectious Agents.** Complete the table below for each of the materials listed as an "infectious agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

| Name and BSL Number of Infectious Agent | a. ABSL Number * | b. Drug Sensitivity Panel Available? (Describe) | c. Select Agent? | | |
|---|---|---|---|---|---|
| | | | Not a Select Agent | Select Agent used in Sub-threshold quantities | Select Agent that Requires Registration/Approval |
| | | (Yes/No) | ( ) | ( ) | ( )** |
| | | (Yes/No) | ( ) | ( ) | ( )** |
| | | (Yes/No) | ( ) | ( ) | ( )** |
| | | (Yes/No) | ( ) | ( ) | ( )** |
| | | (Yes/No) | ( ) | ( ) | ( )** |
| | | (Yes/No) | ( ) | ( ) | ( )** |

*Complete the following for each agent for which the ABSL Number given is less than the BSL Number shown (copy the lines below for each agent):

Name of agent ►
Justification for applying ABSL measures that are less protective than those recommended ►

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**For each "select agent" that requires registration/approval (copy the lines below for each agent):

Name of agent ▶

Registered with CDC or USDA ▶
Registration Number ▶
Registration Date ▶
Expiration Date of Registration ▶

Name of official who granted approval on behalf of VACO▶
Date of approval▶

6. **Biological Agents.** Complete the table below for each of the materials listed as a "biological agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

| Name of Biological Agent | Screening for Infectious Agents |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |

7. **Radioactive Agents.** Complete the table below for each of the agents listed as a "radioactive agent" in the table in Item 1 above (see ACORP App. 3 Instructions, for details).

| Name of Radioactive Agent (specify the isotope) | Authorized Individual | Approving Committee or Official |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

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8. **Agents Containing Recombinant Nucleic Acid.** For each of the materials checked in the table in Item 1, above, as "contains recombinant nucleic acid", indicate which of the conditions applies (see ACORP App. 3 Instructions, for details).

| Name of Agent that Contains Recombinant Nucleic Acid | Subject to the *NIH Guidelines for Research Involving Recombinant DNA Molecules* | Exempt |
|---|---|---|
| | ( ) | ( ) |
| | ( ) | ( ) |
| | ( ) | ( ) |
| | ( ) | ( ) |
| | ( ) | ( ) |
| | ( ) | ( ) |

9. **Potential for Pain or Distress.** Complete the table below for each of the agents listed in Item 1, above, that is expected to have potentially painful or distressing effects on the animals (see ACORP App. 3 Instructions, for details).

| Name of Agent | Nature of Potential Pain/Distress | Measures to Alleviate Pain/Distress |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |

10. **Protection of Animal Facility Staff from Hazardous Materials.** Complete Items 10.a and 10.b, below, for each of the agents listed in the table in Item 1, above, as "toxic", "infectious", "biological", "radioactive", or "contains recombinant nucleic acid" (detailed in Items 4 – 8). This item specifically addresses members of the animal facility staff; protection of the research staff from each of these agents must be addressed in Item G of the main body of the ACORP. See ACORP App.3 Instructions, for details.

    a. Complete the table below.

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| Name of Hazardous Agent | Approving Committee or Official | Institution (VA or affiliate) | Names of Animal Facility Staff Members at Risk |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

b. Detail how the individuals listed in the table above (Item 10.a.) have been (or will be) informed of the possible risks of exposure, and have been (or will be) trained to avoid exposure to these agents.
▶

11. **Signatures.** Provide the applicable signatures on the signature pages (Item Z.3) of the main body of this ACORP.

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**ACORP Appendix 4**
**ANTEMORTEM SPECIMEN COLLECTION**
**VERSION 4**

See ACORP App. 4 Instructions, for more detailed explanations of the information requested.

1. **Summary.** Complete the table below for each specimen to be collected from a live animal on this protocol (see ACORP App. 4 Instructions, for details).

| Specimen Collected | Site and Method of Collection | Anesthesia (Yes/No) | Amount Collected Each Time | Volume Replacement (Yes/No/NA) | Total Number of Collections per Animal | Time Intervals Between Successive Collections |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |

2. **Use of Anesthetics, Tranquilizers, or Analgesics.**

   a. For each specimen described in Item 1, above, as being collected WITHOUT anesthesia, complete Items 2.a(1) and 2.a(2), below:

      (1) Explain why no measures will be taken to prevent pain (e.g., because of scientific requirements described here, or because the collection method involves no more than minor or momentary pain).
      ▶

      (2) Completely describe any method of physical restraint that may be used.
      ▶

   b. For each specimen described in Item 1, above, as being collected WITH anesthesia, complete the following table:

| Anesthetic, tranquilizer, or analgesic agent | Dose (mg/kg) and volume (ml) | Route of administration | Frequency of administration |
|---|---|---|---|
| | | | |
| | | | |

| | | | |
|---|---|---|---|

3. **Volume Replacement for Fluid Collections.**

   a. For each fluid specimen described in Item 1, above, for which NO volume replacement will be provided, explain why not.
   ▶

   b. For each fluid specimen described in Item 1, above, for which volume replacement WILL be provided, describe the replacement fluids that will be administered (including their composition, volume, and route of administration).
   ▶

4. **Monitoring the animals.** Detail how the animals will be monitored after collection of specimens to ensure that they recover appropriately (see ACORP App. 4 Instructions, for details).
   ▶

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**ACORP Appendix 5**
**SURGERY**
**VERSION 4**

See ACORP App. 5 Instructions, for more detailed explanations of the information requested.

1. **Surgery Classification.** Complete the table below for each surgery included in this protocol, and indicate how it is classified (terminal, minor survival, major survival, one of multiple survival). See ACORP App. 5 Instructions, for details.

| Surgery | | Terminal | Survival | | |
|---|---|---|---|---|---|
| # | Description (specify the species, if ACORP covers more than one) | | Minor | Major | One of Multiple* |
| 1 | | ( ) | ( ) | ( ) | ( )* |
| 2 | | ( ) | ( ) | ( ) | ( )* |
| 3 | | ( ) | ( ) | ( ) | ( )* |
| 4 | | ( ) | ( ) | ( ) | ( )* |

*If survival surgery (including major surgeries and any minor surgeries that may induce substantial post-procedural pain or impairment) will be performed as part of this protocol in addition to any other such surgery (on this or another protocol) on the same individual animal, complete items 1.a and 1.b, below:

a. Provide a complete scientific justification for performing the multiple survival surgeries on an individual animal:
▶

b. Give the interval(s) between successive surgeries, and the rationale for choosing the interval(s):
▶

2. **Description of Surgeries.** Describe each surgery listed in Item 1, providing enough detail to make it clear what the effects on the animal will be. (Pre-operative preparation, anesthesia, and post-operative recovery will be covered in items 5, 6, and 7, below.)

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

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Surgery 4 ▶

3. **Personnel.** Complete the table below for each individual who will be involved in any of the surgeries on this protocol.

| Name | Surgery #(s) (see Item 1) | Role in Surgery | | | |
|---|---|---|---|---|---|
| | | Surgeon | Assistant | Manage Anesthesia | Other (describe) |
| | | ( ) | ( ) | ( ) | ( ) |
| | | ( ) | ( ) | ( ) | ( ) |
| | | ( ) | ( ) | ( ) | ( ) |
| | | ( ) | ( ) | ( ) | ( ) |
| | | ( ) | ( ) | ( ) | ( ) |

4. **Location of surgery.** Complete the table below for each location where surgery on this protocol will be performed.

| Building | Room Number | Surgery #(s) (see Item 1) | Type of Space | | |
|---|---|---|---|---|---|
| | | | Dedicated Surgical Facility | Other Dedicated Surgical Space | Other Space not Dedicated to Surgery |
| | | | ( ) | ( )* | ( )* |
| | | | ( ) | ( *) | ( )* |
| | | | ( ) | ( )* | ( )* |
| | | | ( ) | ( )* | ( )* |

*For each space that is not in a dedicated surgical facility, provide the justification for using this space for surgery on this protocol ▶

5. **Pre-operative protocol.**

a. **Pre-operative procedures.** Complete the table below for each pre-operative procedure that will be performed to prepare the animal(s) for surgery.

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| Surgery #(s) (see Item 1) | Fast (Specify Duration) | Withhold Water (Specify Duration) | Place Intravenous Catheter(s) (Specify Site(s)) | Other – Describe |
|---|---|---|---|---|
| 1 | ( ) -- | ( ) -- | ( ) -- | ( ) -- |
| 2 | ( ) -- | ( ) -- | ( ) -- | ( ) -- |
| 3 | ( ) -- | ( ) -- | ( ) -- | ( ) -- |
| 4 | ( ) -- | ( ) -- | ( ) -- | ( ) -- |

b. **Pre-operative medications.** Complete the table below. Include agent(s) for induction of anesthesia, as well as any other pre-treatments that will be administered prior to preparation of the surgical site on the animal.

| Agent | Surgery #(s) (see Item 1) | Dose (mg/kg) & volume (ml) | Route of administration | Frequency of administration (e.g., times/day) | Pre-operative period of treatment (e.g., immediate, or # of days) |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

c. **Pre-operative preparation of the surgical site.** For each surgery, identify each surgical site on the animals, and describe how it will be prepared prior to surgery.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

6. **Intra-operative management.**

# Appendix 9: IACUC/OB Protocol Form

a. **Intra-operative medications.** Complete the table below for each agent that will be administered to the animal during surgery.

| Agent | Paralytic* | Surgery #(s) (see Item 1) | Dose (mg/kg) & volume (ml) | Route of administration | Frequency of dosing |
|---|---|---|---|---|---|
| | ( )* | | | | |
| | ( )* | | | | |
| | ( )* | | | | |

* For each agent shown above as a paralytic, explain why its use is necessary, and describe how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain.
▶

b. **Intra-operative physical support.** For each surgery, describe any physical support that will be provided for the animals during surgery (e.g., warming, cushioning, etc.).
▶

c. **Intra-operative monitoring.** Describe the methods that will be used to monitor and respond to changes in the state of anesthesia and the general well-being of the animal during surgery.
▶

7. **Survival surgery considerations.** For each survival surgical procedure indicated in Item 1 and described in Item 2, complete Items 7.a. – 7.g.

a. Complete the table below for each survival surgery listed in Item 1, above.

| Surgery # (see Item 1) | Survival Period | Measures for Maintaining Sterility | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Sterile Instruments | Surgical Cap | Sterile Gloves | Surgical Scrub | Sterile Drapes | Sterile Gown | Face Mask | Other* |
| | | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( )* |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( )* |
| | | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( )* |
| | | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( )* |

* Describe any "other" measures to be taken to maintain sterility during surgery.
▶

b. For each surgery, describe the immediate post-operative support to be provided to the animals.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

c. Post-operative analgesia. Complete the table below for each surgery listed in item 1, above.

| Surgery # (see Item 1) | Agent* | Dose (mg/kg) & Volume (ml) | Route of Administration | Frequency of Dosing (e.g., times/day) | Period of treatment (e.g. days) |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |

*For each surgery for which NO post-operative analgesic will be provided, enter "none" in the "Agent" column, and explain here why this is justified:
▶

d. Other post-operative medications. Complete the following table to describe all other medications that will be administered as part of post-operative care.

# Appendix 9: IACUC/OB Protocol Form

| Surgery # (see Item 1) | Medication | Dose (mg/kg) & Volume (ml) | Route of Administration | Frequency of dosing (e.g. times/day) | Period of treatment (e.g. days) |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

e. Post-operative monitoring. After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.

(1) Immediate post-operative monitoring

| Surgery # (see Item 1) | Frequency of Monitoring | Duration at this Frequency | Name(s) of Responsible Individual(s) |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |

(2) Post-operative monitoring after the immediate post-operative period

| Surgery # (see Item 1) | Frequency of Monitoring | Duration at this Frequency | Name(s) of Responsible Individual(s) |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

| | | | |
|---|---|---|---|
| | | | |

f. Post-operative consequences and complications.

(1) For each surgery, describe any common or expected post-operative consequences or complications that may arise and what will be done to address them.

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

(2) List the criteria for euthanasia related specifically to post-operative complications:

Surgery 1 ▶

Surgery 2 ▶

Surgery 3 ▶

Surgery 4 ▶

(3) In case an emergency medical situation arises and none of the research personnel on the ACORP can be reached, identify any drugs or classes of drugs that should be avoided because of the scientific requirements of the project. (If the condition of the animal requires one of these drugs, the animal will be euthanatized instead.)
▶

g. Maintenance of post-surgical medical records. Complete the table below for each surgery, specifying where the records will held, and identifying at least one individual who will be assigned to maintain accurate, daily, written post-surgical medical records. Indicate whether the named individuals are research personnel involved in this project, or members of the veterinary staff.

# Appendix 9: IACUC/OB Protocol Form

| Surgery # (see Item 1) | Location of Records | Name(s) of Individual(s) Responsible for Maintaining Written Records | Research Personnel | Veterinary Staff |
|---|---|---|---|---|
| 1 | | | ( ) | ( ) |
| 2 | | | ( ) | ( ) |
| 3 | | | ( ) | ( ) |
| 4 | | | ( ) | ( ) |

8. **Certification.** The PI must sign the certification statement in Item Z.5 of the main body of the ACORP.

# Appendix 9: IACUC/OB Protocol Form

**ACORP APPENDIX 6**
**SPECIAL HUSBANDRY AND PROCEDURES**
**VERSION 4**

See ACORP App. 6 Instructions, for more detailed explanations of the information requested.

1. **Description of Procedures.** Complete the table below for each procedure listed in Item V of the main body of the ACORP that is not detailed in a SOP or in another item or Appendix of the ACORP. For each special procedure, check all features that apply.

| Special Procedure | | Features | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Number | Brief Description | Husbandry | Restraint | Noxious Stimuli | Exercise | Behavioral Conditioning | Irradiation | Imaging | Other** |
| 1 | | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) |
| 2 | | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) |
| 3 | | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) |
| 4 | | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) | ( ) |

*Husbandry refers to all aspects of care related to the maintenance of the animals, including (but not limited to) provision of an appropriate diet, access to water, control of environmental conditions, and the selection of primary and secondary enclosures.

**Describe any "Other" features that are involved.
▶

a. Provide a complete description of each special procedure listed above, including the duration of the procedure, how frequently it will be repeated in any one animal, and any effects it is expected to have on the animal:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

b. Explain why each of these special procedures is necessary:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

2. **Personnel.** Complete the table below for each special procedure listed in Item 1, above. Identify the individual(s) who will be responsible for carrying out the procedures, and those who will be responsible for monitoring the condition of the animals during and after the procedures. After-hours contact information for the personnel listed must be provided to the veterinary staff for use in case of an emergency.

| Procedure Number (see Item 1) | Responsible Individual(s) | |
|---|---|---|
| | Carrying Out Procedure | Monitoring the Animals |
| 1 | | |
| 2 | | |

| | | |
|---|---|---|
| 3 | | |
| 4 | | |

3. **Potential Pain or Distress.** Complete the table below for each special procedure identified in Item 1, above, indicating for each procedure, whether potential pain and/or distress is expected, and, if so, describing the potential pain and/or distress and indicating whether any measures are to be taken to prevent or alleviate it.

| Procedure Number (see Item 1) | Expected Potential Pain and/or Distress | | | |
|---|---|---|---|---|
| | No | Yes | | |
| | | Description | To Be Relieved | Not to Be Relieved |
| 1 | ( ) | | ( )[a] | ( )[b] |
| 2 | ( ) | | ( )[a] | ( )[b] |
| 3 | ( ) | | ( )[a] | ( )[b] |
| 4 | ( ) | | ( )[a] | ( )[b] |

a. For each procedure for which potential pain and/or distress is expected, but WILL be prevented or alleviated by administration of the analgesic(s) or stress-relieving agents, complete the table below:

| Procedure Number (see Item 1) | Agent | Dose (mg/kg) & vol (ml) | Route of admin | Freq of admin (times/day) | Duration of admin (days post-procedure) |
|---|---|---|---|---|---|
| 1 | | | | | |
| 2 | | | | | |
| 3 | | | | | |
| 4 | | | | | |

Describe any non-pharmacological measures to be taken to address the potential pain and/or distress:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

b. For each procedure for which potential pain and/or distress is expected and <u>will NOT be prevented or alleviated</u>, provide the scientific justification for this:

Special Procedure 1 ▶

Special Procedure 2 ▶

Special Procedure 3 ▶

Special Procedure 4 ▶

4. **Monitoring.** Describe how the condition of the animals will be monitored during and after each of the special procedures, and list the criteria that will be used to determine when individual animals will be removed from groups undergoing these procedures, because of pain or distress (see ACORP App. 6 Instructions, for details):

| Procedure Number (see Item 1) | Monitoring Methods | Endpoint Criteria |
|---|---|---|
| 1 | | |
| 2 | | |
| 3 | | |
| 4 | | |

# Appendix 9: IACUC/OB Protocol Form

**ACORP APPENDIX 7**
**USE OF PATIENT CARE EQUIPMENT AND/OR AREAS**
**FOR ANIMAL STUDIES**
**Version 4**

See ACORP App. 7 Instructions, for more detailed explanations of the information requested.

1. **Full Name(s) of Principal Investigator(s)** ▶

2. **Equipment to be Used.**

   a. Identify the equipment ▶

   b. Procedure(s) to be performed with this equipment ▶

   c. Describe how contamination of the human patient care equipment will be prevented and how the equipment will be cleaned/sanitized before its subsequent use for human patients:
   ▶

3. **Human Patient Care Procedural Areas to be Used.**

   a. Location(s) ▶

   b. Animal species to be studied or treated ▶

   c. Number of individual animals to be studied or treated ▶

   d. Date(s) ▶

   e. Time(s) of day ▶

   f. Procedure(s) to be performed on the animals in these areas ▶

   g. Protection and cleaning of patient care room surfaces ▶

   h. Benefits to VA patients. Briefly describe how this use of the human patient care areas for research on animal subjects potentially benefits VA patients.

▶

i. Necessity for use of human patient care areas. Explain why this work on animal subjects cannot be performed within the animal facility or a research laboratory area.
▶

j. Animal transport. Describe how the animals will be transported back and forth between the animal housing area and the human patient care areas.
▶

k. Preventing human patients and patient care personnel from being affected by the presence of the animals. Provide detailed descriptions of the measures to be taken to address noises and odors, allergens, and zoonotic pathogens associated with the animals.
▶

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.7) of the main body of this ACORP.

# Appendix 9: IACUC/OB Protocol Form

**ACORP APPENDIX 8**
**USE OF EXPLOSIVE AGENT(S) WITHIN THE VMU OR IN ANIMALS**
**VERSION 4**

See ACORP App. 8 Instructions, for more detailed explanations of the information requested.

1. **Full name(s) of Principal Investigator(s) ►**

2. **Explosive agents to be used.**

   a. Identify the explosive agents. Complete the table below.

| Agent Number | Name(s) Used to Refer to the Agent in This ACORP | Name Shown for this Agent on the MSDS on File | CAS number | Location of the MSDS on File |
|---|---|---|---|---|
| 1 | | | | |
| 2 | | | | |
| 3 | | | | |
| 4 | | | | |

   b. Locations where the explosive agents will be used. Complete the table below.

| Agent Number | Location Where Agent Will Be Used | | | |
|---|---|---|---|---|
| | Building | Room Number | Within the VMU | Outside of VMU |
| 1 | | | ( ) | ( ) |
| 2 | | | ( ) | ( ) |
| 3 | | | ( ) | ( ) |
| 4 | | | ( ) | ( ) |

   c. Procedure(s) to be performed. Briefly describe the use of each of the explosive agents on this protocol and explain why it is necessary to use these agents (why non-explosive replacements cannot be used instead).
   ►

d. Precautions to be taken to prevent explosions. Describe the measures to be taken to store, use, and dispose of safely each explosive agent and any materials contaminated with it, and to prevent the generation of sparks in its presence. See ACORP App. 8 Instructions, for a list of commonly used precautions.
▶

e. Period of use.
Beginning no earlier than (date) ▶
Ending no later than (date) ▶

f. Animals that will be administered explosive agents:
Species ▶
Approximate weights of individual animals ▶
Approximate number of animals ▶

3. **Personnel.** Complete the table below for each individual who will handle any of the explosive agents as part of this protocol.

| Name of Individual | Explosive Agent(s) to be Handled | Training and Experience Pertinent to Handling Explosive Agents |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

4. **Signatures.** Provide the signatures required on the signature pages (Item Z.8) of the main body of this ACORP.

# Appendix 9: IACUC/OB Protocol Form

**ACORP Appendix 9**
**DEPARTURES FROM "MUST" AND "SHOULD" STANDARDS IN THE *GUIDE (2011)***
**VERSION 4**

See ACORP App. 9 Instructions, for more detailed explanations of the information requested.

For each IACUC-approved "departure" of this protocol from a "Must" or "Should" standard in the *Guide*, provide the following information. (Consult the IACUC or the Attending Veterinarian for help in determining whether any "departures" are involved.):

Copy the lines below for each departure.

Briefly summarize the "Must" or "Should" standard, and provide the number(s) of the page(s) on which it appears in the *Guide*
▶

Describe the specific alternate standard(s) that will be met on this protocol, and how they will be monitored.
▶

Provide the scientific, veterinary medical, or animal welfare considerations that justify this departure
▶

## Appendix 10: IACUC/OB Periodic Report

Please attached a copy of the latest facilities (including laboratory inspections) and program assessment report conducted by the IACUC/OB.

# See Attachment #2

# Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

Summarize the heating, ventilation and air conditioning (HVAC) systems for each animal facility, ***including all satellite facilities***. Include ***all animal holding rooms*** (including satellite holding rooms), surgical facilities, procedure rooms, and support spaces integral to animal facilities (e.g., cage wash, cage and feed storage areas, necropsy, treatment).

| **Location/Building/Facility:** | |
|---|---|

In the text box below, provide a general description of the mechanical systems used to provide temperature, humidity and air pressure control. Include details such as:

- the source(s) of air and air recirculation rates if other than 100% fresh air
- treatment of air (filters, absorbers, *etc.*)
- design features such as centralized chilled water, re-heat coils (steam or hot water), individual room vs. zonal temperature and relative humidity control, the use of variable air volume (VAV) systems and other key features of HVAC systems affecting performance
- features that minimize the potential for adverse consequences to animal well-being (such as re-heat coils that fail closed or that are equipped with high-temperature cut-off systems), and
- how room temperature, ventilation, and critical air pressures are monitored and maintained in the event of a system or component failure, including notifying appropriate personnel in the event of a significant failure that occurs outside of regular working hours and/or other management systems used to respond to alerts or failures.

- Source of Air: 100% Fresh-NA
- Air Treatment: Air Filters
- Design Features:
  Chilled Water and re-heat coils are utilized in the VMU for cooling and heating. Steam from boilers are used for humidity throughout the building. Relative humidity control is zonal throughout the building. (See building map attachment)
- Features:
  The modulating heating valve at each reheat coil is opened or closed as needed to match the estimated valve position to the heating signal. In the event of loss of communication, the valves for the animal holding rooms fail closed. Heat to the reheat coils is provided by the hot water heating loop. If the room temperature is greater than the supply air temperature, the reheat valve will go to full open and AHU-1(Air Handler Unit-1) will turn off.

## Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

- Monitoring:

  Air temperature sensors on the inlet and outlet of each energy recovery coil monitor the entering and leaving air temperatures. Water temperature sensors on the inlet and outlet of each energy recovery coil monitor the water temperature entering and leaving each coil. Differential pressure monitors monitor the pressure drop across the air filters upstream of the energy recovery coils. Mechanical equipment is tied to the DDC alarm system that will notify personnel via cell phone alert. Personnel are available 24/7/365 for response to DDC alarms.
  If a supply fan has been activated for at least 120 seconds and the status if OFF, a Fan alarm is triggered. The Fan Alarm must be manually reset from a display, or by cycling power to the VLC.

  If both Supply Fans are in Alarm, the Low Limit temperature is in Alarm, the Manual Disable Command is issued, the freeze stat is tripped, or any reheat coil alarm is ON (according to reheat alarm sequence below), fan operation is locked out. A fan override switch allows the supply fans to be enabled even if one of the lockouts is active.

  The filter differential pressure sensors for the pre-filter and final filters are displayed at the operator's terminal. If the setpoint pressures are exceeded, the filter alarm is activated and a pop-up alarm is initiated. Along with the energy reclaim coils, filters were installed upstream of each coil. The filter pressure drop are displayed on the heat reclaim coil loop page.

In the Table below, provide room-specific information requested. For each room within this location, indicate use, including the species for animal housing rooms. *Measurement of air exchange rates and verification of relative pressure within animal housing rooms (excluding rooms housing aquatic species only) and cage washing facilities must be completed* ***within the 12 months preceding completion of this Program Description.*** Air exchange rates may be important to maintain air quality in other areas; *however, measurements may be left at the discretion of the institution.* Information may be provided in another format, providing all requested data is included. **[*Note*: Please remove the examples provided in the Table below.]**

| **Room No.** | **Specific Use** | **Temperature Set-Point** (define units) | **Electronic / Emergency Monitoring of Temperatures** (Y/N) | **Alert/Alarm Temperature Ranges** (if applicable; define units) | **Humidity Control** (Y/N) | **Relative Pressure** | **Air Exchange Rate** (per hour) | **Date Verified / Measured** |
|---|---|---|---|---|---|---|---|---|

# Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

| | | (settings to be verified) | | | | | (values to be measured) | |
|---|---|---|---|---|---|---|---|---|
| (b)(6) | Photo microscope Room(Hysto Lab) | 73°F | Yes | 3° F above or below | Yes | + | 10-15 per hour | 2/18 |
| (b)(6) | Surgery room (storage) | 73°F | Yes | 3° F above or below | Yes | + | 10-15 per hour | 2/18 |
| (b)(6) | Dr. Bauer-(Hysto Office) | 73°F | Yes | 3° F above or below | Yes | + | 10-15 per hour | 2/18 |
| (b)(6) | Corridor-storage | 73°F | Yes | 3° F above or below | Yes | neutral | 10-15 per hour | 2/18 |
| (b)(6) | Storage-surgery supplies | 73°F | Yes | 3° F above or below | Yes | neutral | 10-15 per hour | 2/18 |
| (b)(6) | General Lab-shared | 70°F | Yes | 3° F above or below | Yes | + | 10-15 per hour | 2/18 |
| (b)(6) | Lab-microscope | 73°F | Yes | 3° F above or below | Yes | + | 10-15 per hour | 2/18 |
| (b)(6) | Dirty Room-Cage Washing | 73°F | Yes | 3° F above or below | Partial | - | 10-15 per hour | 2/18 |
| (b)(6) | Janitorial Room | 73°F | Yes | 3° F above or below | Yes | neutral | 10-15 per hour | 2/18 |
| (b)(6) | Trash receptacle area-exterior | NA | NA | NA | Yes | NA | 10-15 per hour | 2/18 |
| (b)(6) | Animal Chute-exterior | NA | NA | NA | Yes | NA | 10-15 per hour | 2/18 |
| (b)(6) | IVIS Room/Animal Room | 73°F | Yes | 3° F above or | Yes | - | 10-15 per | 2/18 |

# Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

| Room No. | Specific Use | Temperature Set-Point (define units) | Electronic / Emergency Monitoring of Temperatures (Y/N) | Alert/Alarm Temperature Ranges (if applicable; define units) | Humidity Control (Y/N) | Relative Pressure | Air Exchange Rate (per hour) | Date Verified / Measured |
|---|---|---|---|---|---|---|---|---|
| | | | | below | | | hour | |
| (b)(6) | Alcove outside-exterior | NA | NA | NA | Yes | NA | 10-15 per hour | 2/18 |
| (b)(6) | Storage-no climate control | NA | NA | NA | Yes | neutral | 10-15 per hour | 2/18 |
| (b)(6) | NA-Engineering Room | NA | NA | 3° F above or below | Yes | NA | 10-15 per hour | 2/18 |
| (b)(6) | Electrical Room only | NA | NA | 3° F above or below | Yes | NA | 10-15 per hour | 2/18 |
| (b)(6) | Animal Treatment Room Pod #3-Mice | 71°F | Yes | 3° F above or below | Yes | - | 10-15 per hour | 2/18 |
| (b)(6) | Animal Treatment Room Pod #3-Mice | 71°F | Yes | 3° F above or below | Yes | - | 10-15 per hour | 2/18 |
| (b)(6) | Animal Treatment Room Pod #3-Mice | 71°F | Yes | 3° F above or below | Yes | - | 10-15 per hour | 2/18 |
| (b)(6) | Animal Treatment Room Pod #3-Mice | 71°F | Yes | 3° F above or below | Yes | - | 10-15 per hour | 2/18 |
| (b)(6) | Lab | 72°F | Yes | 3° F above or below | Yes | + | 10-15 per hour | 2/18 |

# Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Su

| Room No. | Specific Use | Temperature Set-Point (define units) | Electronic / Emergency Monitoring of Temperatures (Y/N) | Alert/Alarm Temperature Ranges (if applicable; define units) | Humidity Control (Y/N) | Relative Pressure | Air Exchange Rate (per hour) | |
|---|---|---|---|---|---|---|---|---|
| (b)(6) | Atto Clave Alcove-open hall | 70oF | Yes | 3o F above or below | Yes | Open hall | 10-15 per hour | 2/18 |
| (b)(6) | Lab-storage | 72oF | Yes | 3o F above or below | Yes | neutral | 10-15 per hour | 2/18 |
| (b)(6) | Animal Housing Room Pod #2-Mice | 74oF | Yes | 3o F above or below | Yes | + | 10-15 per hour | 2/18 |
| (b)(6) | Animal Housing Room Pod #2-Mice | 71oF | Yes | 3o F above or below | Yes | + | 10-15 per hour | 2/18 |
| (b)(6) | Storage-facility supplies | 71oF | NA | 3o F above or below | Yes | neutral | 10-15 per hour | 2/18 |
| (b)(6) | Animal Housing Room Pod #1-Mice | 71oF | Yes | 3o F above or below | Yes | + | 10-15 per hour | 2/18 |
| (b)(6) | Animal Housing Room Pod #1-Mice | 71oF | Yes | 3o F above or below | Yes | - | 10-15 per hour | 2/18 |
| (b)(6) | Lab-not in use | 71oF | Yes | 3o F above or below | Yes | + | 10-15 per hour | 2/18 |
| (b)(6) | Animal Housing Room Pod #1-Mice | 71oF | Yes | 3o F above or below | Yes | + | 10-15 per hour | 2/18 |
| (b)(6) | Animal Housing Room Pod #1-Mice | 71oF | Yes | 3o F above or below | Yes | + | 10-15 per hour | 2/18 |

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# Appendix 11: Heating, Ventilation and Air Conditioning (HVAC) System Summary

| Room No. | Specific Use | Temperature Set-Point (define units) | Electronic / Emergency Monitoring of Temperatures (Y/N) | Alert/Alarm Temperature Ranges (if applicable; define units) | Humidity Control (Y/N) | Relative Pressure | Air Exchange Rate (per hour) | Date Verified / Measured |
|---|---|---|---|---|---|---|---|---|
| (b)(6) | Animal Housing Room Pod #1-Mice | 71°F | Yes | 3° F above or below | Yes | + | 10-15 per hour | 2/18 |
| (b)(6) | Feed Room | 68°F | Yes | 3° F above or below | No | + | 10-15 per hour | 2/18 |
| (b)(6) | Storage-supplies for caging | NA | NA | 3° F above or below | Yes | + | 10-15 per hour | 2/18 |
| (b)(6) | Clean Room-Cage washer and cage set-up. | 70°F | Yes | 3° F above or below | Yes | + | 10-15 per hour | 2/18 |

[Create additional rows by pressing TAB in the bottom-right box.]

***Copy and repeat the Description and Table for each location, including all satellite housing locations.***

# Appendix 12: Aquatic Systems Summary – Part I

Please summarize water management and monitoring information programs for each animal facility, including all satellite facilities, rooms, enclosures. The following key will assist [illegible] form:

(1) List location of aquaria, including outdoor [illegible] If indoors, list building and room number. Note that all species housed at the sa[illegible]n and monitoring may be listed in the same row.

(2) Please indicate if embryonic (E[illegible]

(3) Group tanks (ponds, outdoo[illegible]r supply; individual aquaria have exclusive water hand[illegible]

(4) Indicate water type, e.g.,[illegible]

(5) Indicate water pre-treat[illegible]

(6) Indicate water circulati[illegible]applicable, indicate water exchange frequ[illegible]

(7) Provide a key word f[illegible]hanical-bead filter). A diagram may be p[illegible]nt replaced daily.

NOT APPLICABLE

**Part I**

| Location (1) | Spe (2) | | | | | n | Disinfection (e.g., UV, ozone) |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

*Note:* Records of equipment maintenance (filter changes, UV bulb changes, probe changes, calibrations, *etc.*) should be available for review.

[Create additional rows by pressing TAB in the bottom-right box.]